ELISA PLATE READER

DIA2000

Version – 3.400A

DIAsource ImmunoAssays S.A.
Rue du Bosquet 2 B-1348 Louvain-La-Neuve
BELGIUM
Phone : +32 10 84 99 11
Fax : +32 10 84 99 90
www.diasource.be
IVDInstrumentation.support@diasource.be.

IVD

CE

TABLE OF CONTENTS

1. GENERAL INFORMATION *5*

1.1. Warranty Information **5**

1.2. Technical Service **5**

1.3. Contacts **5**

2. GENERAL SAFETY WARNINGS *6*

2.1. Danger – warning symbols **6**

2.2. Use of the Instrument **7**

3. INTRODUCTION *8*

3.1. Description **8**

3.2. Special Features **8**

3.3. Technical Specification **9**

4. PACKAGING, TRANSPORT AND STORAGE *11*

4.1. General Warnings **11**

4.2. Packaging **11**

4.3. Instrument Transportation **11**

4.4. Storage of Instrument **11**

5. INSTRUMENT DESCRIPTION *12*

5.1. Instrument Working Principle **12**

5.2. Perspective View **14**

5.3. Keypad **15**

6. INSTALLATION PROCEDURE AND VERIFICATION CRITERIA *17*

6.1. Unpacking Instructions **17**

6.2. Placing the Instrument **17**

6.3. Power Supply Requirements **17**

6.4. Protective Grounding 17

6.5. Printer 17

6.6. Start up Instructions 19

6.8. Micro Titer Plate Carriage 21

6.9. Plate Loading & Pipetting Procedure 21

6.10. Readings Check 22

7. PRECAUTIONS 22

8. PROGRAMMING MODES 23

8.1. Absorbance Mode 23

8.2. Single Standard 26

8.3. Cut Off Mode 27

8.4. Reverse Cut Off Mode 43

8.5. Multi Standard Mode: 44

8.6. Percentage Absorbance 55

8.7. Uptake 55

8.8. Kinetic 56

9. RECALLING AND RUNNING OF STORED TEST/PROGRAMS 57

9.1. Absorbance Mode: 58

9.2. Cut off Mode 62

9.3. Multistandard 69

10. RERUNNING ACCEPTED TESTS / PROGRAMS 81

11.SAMPLE AND SAMPLE DUPLICATE 85

12.PATIENT IDENTITY / SAMPLE IDENTITY ENTRY 87

13.SAVE PLATE AND SAVE RESULTS 90

14.VIEW STORED DATA 92

15. UTILITIES 94

15.1. Date & Time Setting 95

15.2. Program Filter 95

15.3. Printer On / Off setting: 96

15.4. Enter Clinic Name: 96

15.5. Shaker (Plate Shaking Mode) 97

15.6. Communication Settings: 98

15.8. Install USB Driver: 99

15.9. Auto Print: ON 99

15.10. PASSWORD: 100

16. SERIAL COMMUNICATION ***103***

17.1. Clear Memory 109

17.2. Lamp Amplitude 110

17.3. Printer Self test 112

19. DECONTAMINATION ***115***

19.1. Decontamination Procedure 115

19.2 Purpose of Decontamination 115

19.3. General Considerations 115

19.4. Procedure 115

20. SAFETY CLEARANCE CERTIFICATE ***116***

1. GENERAL INFORMATION

1.1. Warranty Information

Each Instrument is completely tested and guaranteed for twelve months from delivery
The warranty applies to all the mechanical and electrical parts. It is valid only for proper installation, use and maintenance in compliance with the instructions given in this manual.

DIASOURCE IMMUNOASSAYS S.A. will, at its discretion repair or replace parts, which may be found defective in the warranty period. The warranty does not include any responsibility for direct or indirect personal and material damages, caused by improper use or maintenance of the instrument.

Parts that are inherently subject to deterioration are excluded from the warranty. In case of defects due to misuse of the instrument, any travel and man-hour expenses will be charged extra.

1.2. Technical Service

DIASOURCE IMMUNOASSAYS S.A. is always accessible to the customers for any kind of information about installation, use, maintenance and others. When asking for service, please refer to this manual and report the data reported on the identification label (serial number).

Only qualified technicians are entitled to repair instruments. The user should carry out ordinary maintenance.

1.3. Contacts

DIASOURCE IMMUNOASSAYS S.A.

Rue du Bosquet 2
BE-1348 Louvain-La-Neuve
BELGIUM

IVD Instrumentation Support Service
Hotline phones availabilities : Monday to Friday; 08 :30 to 17:00 (Belgium time)
Please contact first Hotline 1. In case of no response please contact Hotline 2.
Hotline 1 phone number : 0032 (0)10 849932
Hotline 2 phone number : 0032 (0)10 849976
Fax : 0032 (0)10 849990
Email : IVDInstrumentation.support@diasource.be

2. GENERAL SAFETY WARNINGS

2.1. Danger – warning symbols

This is a symbol of generic danger. It means that, serious damage can occur to the operator if described precautions are not observed.

This is a symbol of HIGH ELECTRIC VOLTAGE. It is dangerous to touch any part having this label. Only qualified operators can access these components, after unplugging the instrument from the supply.

This symbol indicates that the instrument makes use of chemical reagents and other dangerous (Corrosive, irritant, or harmful) CHEMICAL SUBSTANCES, which can cause damage to people or materials. When this label is found, pay attention to the manufacturer's recommendations**.**

This symbol indicates that the instrument involves the handling of samples, which can be infected (urine or human serum). In this condition, infection or contamination might occur. Pay attention to the general safety warnings when in presence of such biological substances. Use protective clothes, gloves and glasses.

This symbol in the user manual indicates that damages to the instrument or erroneous results could occur if the given warnings are not respected.

This symbol indicates a portion, which is particularly important, and should be studied carefully.

This symbol indicates a Protective Earth or Ground terminal.

2.2. Use of the Instrument

1. The instrument has to be used for the designed purposes under specified conditions, following proper procedures and safety rules by qualified personnel.

2. This manual contains instructions for operation performed by qualified personnel.

3. A qualified user has to make sure that environmental condition is suitable, the installation is correct, the use and maintenance are proper according to the general safety rules as well as to the particular precautions described in the manual. (However, he is not entitled to repair the instrument).

4. A qualified technician is entitled to maintain and repair the instrument using the original spare parts according to the given instructions.

5. Maintain room temperature and humidity as specified in the manual.

6. If the instrument is not used as described in the manual, the protection provided by the instrument may be impaired.

7. Alterations to the instrument are prohibited. The user is liable for any improper Modification to the instrument, and for the deriving consequences.

8. Contact the MANUFACTURER service or authorized service center in case the instrument need extraordinary maintenance. Specialized technicians who will be able to repair the instrument using original spare parts will carry out the maintenance.

9. This IVD equipment complies with the emission and immunity requirements as per IEC61326 series.

10. Warning : This equipment has been designed and tested to CISPER11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference."

11. An advisory that the electromagnetic environment should be evaluated prior to operation of the device.

12. Warning : Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded international RF sources), as these may interfere with the proper operation.

3. INTRODUCTION

3.1. Description

The ELISA PLATE READER is a user friendly micro plate Analyser. It is compact & lightweight. It is designed to measure and interpret enzyme immunoassay results, both monochromatically and bichromatically. It is intended for in vitro diagnostic use.

3.2. Special Features

The ELISA READER can accommodate a flat bottom as well as a round configuration. The carriage is designed in a way that the plate automatically moves smoothly and positions iself accurately in the optical measurement path. Readings are taken continuously. The average value is calculated and results are presented according to the option selected.

The ELISA READER operates on a WIDE voltage (90-270 volt). This eliminates the need for an external voltage stabilizer**.**

The ELISA READER has a special provision, which allows it to be used even when a printer is not available. Readings can be conveniently noted down manually.

The other special features of ELISA READER are as follows:

- Option of Lamp saving mode.
- Selection of both primary and secondary filters.
- Latest technology with battery back-up for 250 tests with QC, more than 2500 result.
- Robust built in 52-column thermal printer with 384 stationary heads.
- Unique circuitry for long lamp life.
- Alphanumeric Patients ID entry.
- Editing of saved tests.
- Human machine user interface: Touch panel, Keypad
- Multi-standard curve up to 12 standard calibrations with one blank optional.
- Access to test by touch of key.
- Capability to connect to 80-column printer for direct report printout.
- Blank is optional.
- Setting of the Date and Time.
- Capable of storing, deleting and recalling tests.
- Multiple calibrator modes.
- Selection of duplicates for both calibrators and samples.
- Extensive software for cut off mode.
- Selection of Positive, Equivocal, Negative cut-off.

- Several pre-programmed calculation modes will help to facilitate data processing of enzyme immunoassays. These are menu driven modes for simple and error free operations.

  - ✓ ABSORBANCE MODE
  - ✓ CUT-OFF MODE
  - ✓ MULTISTANDARD MODE
  - ✓ SINGLE CALIBRATOR MODE
  - ✓ % ABSORBANCE MODE
  - ✓ UPTAKE
  - ✓ KINETIC

3.3. Technical Specification

Human Machine Interface	**TOUCH PANEL / KEYPAD**
Linear measurement range	**0.000 to 3.000 Absorbance Units (A)**
Photometric Accuracy	± 2% or 0.007 whichever is higher, from 0 to 1.5 A ± 3% from 1.5 A to 3.0 A
Drift	<0.005 A/hr
Photometric Linearity	2.5 A
Optical measurement	8 Channel
Filters Type of filter Wave Length Half Bandwidth Selection	 Narrow band Interference 405nm, 450nm, 492nm, 630nm, 560nm 10nm ± 2nm Automatic by Stepper Motor
Light Source Display Curve Plotting	Tungsten halogen lamp, 20 Watts 6” Graphics LCD, Negative Blue, STN Graphical Representation on Printer

Plate Carrier Movement	Precisely through the stepper motor
Printer	Built in Thermal Printer 52 columns
Memory	Battery backup supporting 2500 open channels 64 KB Non Volatile RAM
Analysis Mode	Absorbance Single Standard Cut-off Multi-Standard % Absorbance Uptake Kinetic
Connectivity / RS232 Serial Port / USB	9600 baud, 8 data, 1 stop, no parity bits / USB
Power Wattage Voltage	75 Watts 115-230 Volt ± 10%, 50/60 hz.
Operation Position	On horizontal flat, rigid and vibration free surface
Operating Conditions Temperature Relative Humidity	From + 18°C to 35°C Up to 80%
Storage Conditions Temperature Relative Humidity	From -10°C to 40°C Up to 80%
Enclosure	ABS Fire Retardant
Size (cm)	36 x 36 x 22 (lxbxh)
Weight (Approx.)	10 Kgs

4. PACKAGING, TRANSPORT AND STORAGE

4.1. General Warnings

Instrument has to be decontaminated before packing for transportation.

4.2. Packaging

Packaging is needed whenever the instrument is to be transported or shipped by courier or other purposes.

To pack the instrument the following instructions has to be followed:

1. Decontaminate the instrument as explained on decontamination chapter of this manual.
2. Put the instrument into the original packaging box; Instrument has to be properly protected by plastic protective material. Put copy of Safety clearance certificate (copy of Safety clearance certificate is attached at the end of this manual)
3. Mark the packaging with address, instrument identification and warning labels

4.3. Instrument Transportation

The transportation of the instrument in unpacked condition must be limited within the room where it is used, to avoid damage.

4.4. Storage of Instrument

Before storing the instrument for a long period, pack it carefully as described above and store indoors.

Relative humidity can be up to 80%, and temperature between -10ºC and 40ºC.

5. INSTRUMENT DESCRIPTION

5.1. Instrument Working Principle

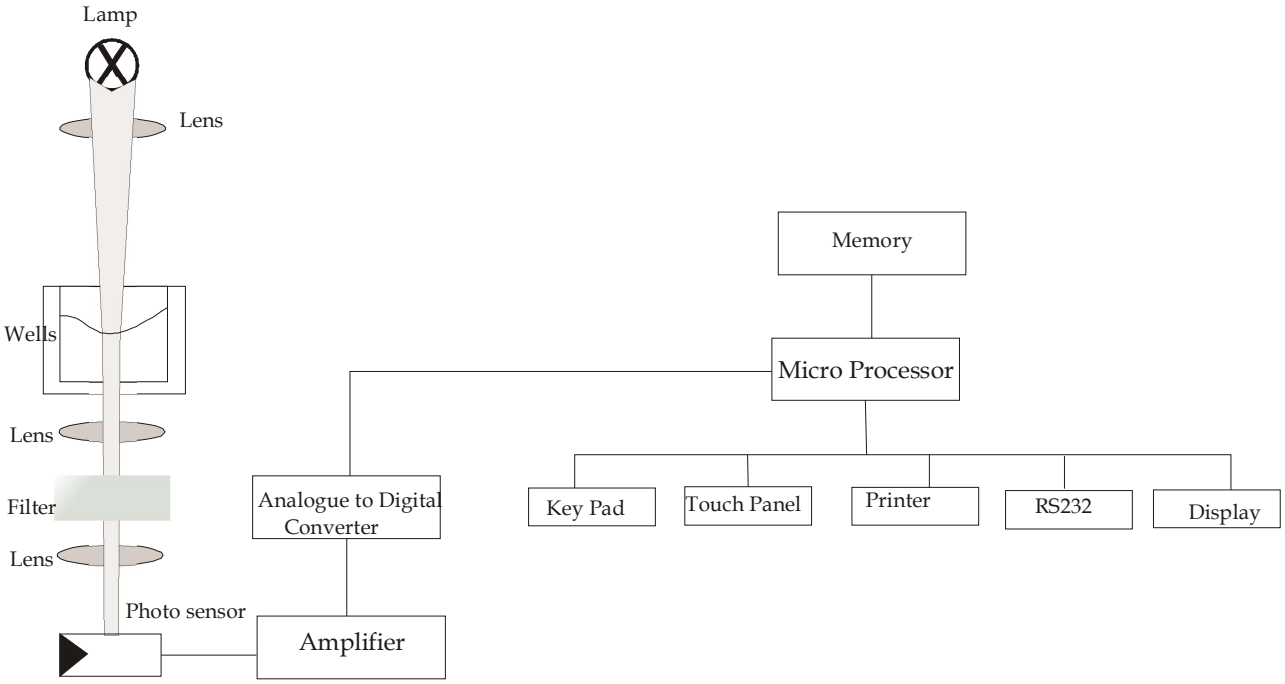
1. Switch on and program the instrument.
2. Place the plate firmly onto the carriage.
3. Start the test, the plate will be conveyed inside and strip is placed precisely below the optical path. The measurement is carried out step by step.
    - At the end of the cycle the results are printed at the same time they are available at the RS232 serial port output.

On starting the test, the plate will be conveyed into the instrument.

Plate is moved in step by step by a well-controlled mechanism and each well is positioned precisely below the optical path. Optical density of each well is measured as explained below. Based on selected programming mode, sophisticated algorithms are used for analyzing the measured value and presenting the same on the printer, display & RS232 serial port for computer Interface.

The following diagram represents the main functional elements of the instrument:

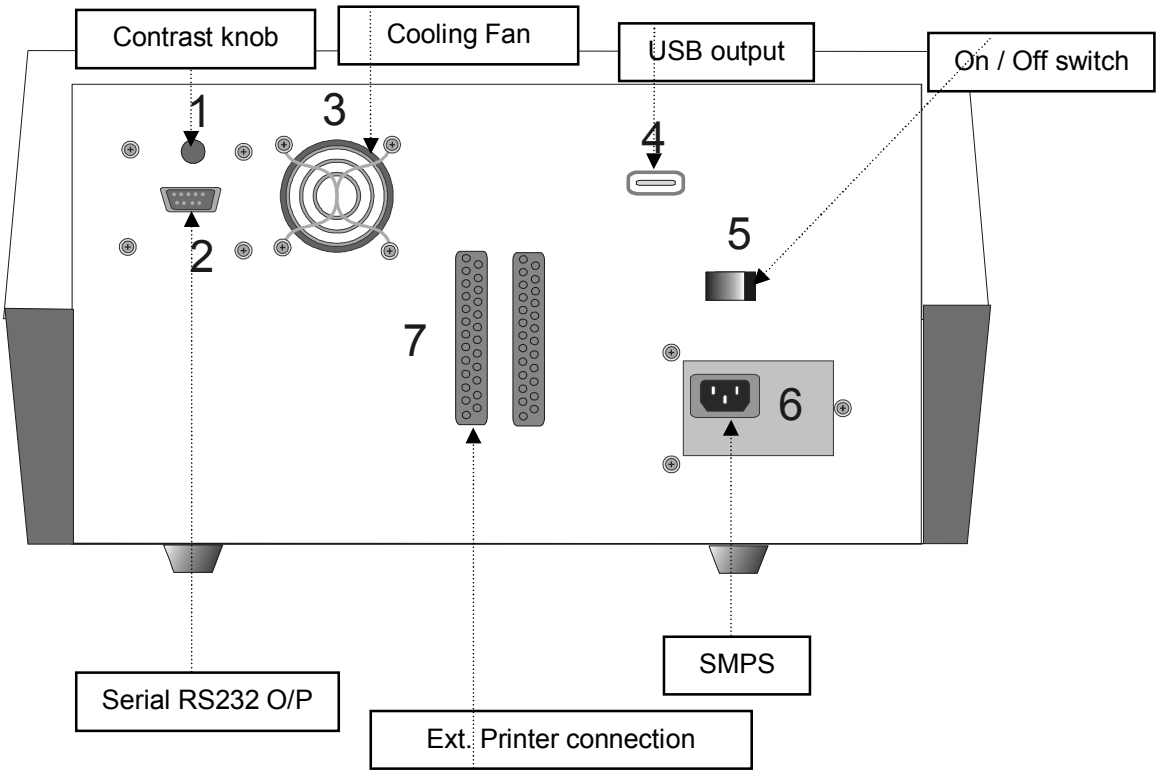
White light produced by the lamps is focused into a beam by the lens and passes through the sample. Part of the light is absorbed by the sample and the remaining light is transmitted. It is filtered by interference filters and focused onto the photodiodes. The photodiode converts the received light into an electrical signal which is transformed into a digital form, from which the microprocessor calculates the absorbance, taking in account of the blank and bichromatic selection.


Lamp
Lens
Wells
Lens
Filter
Lens
Photo sensor
Amplifier
Analogue to Digital Converter
Memory
Micro Processor
Key Pad
Touch Panel
Printer
RS232
Display

5.2. Perspective View

Front View:

Rear View:



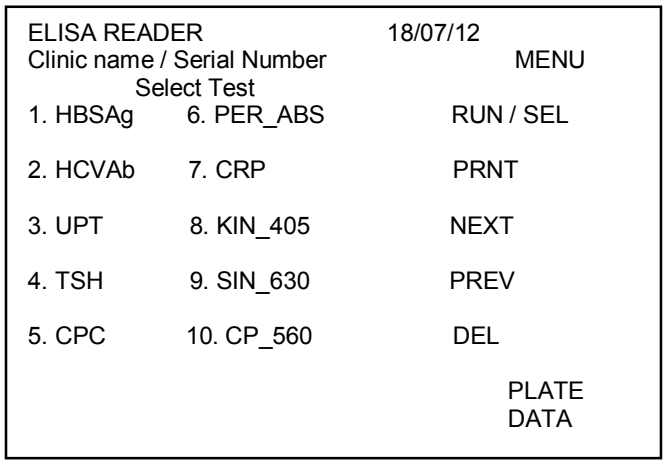
1) Contrast Knob-use to adjust display contrast

2) Serial RS232 output 3) Cooling Fan 4) USB output

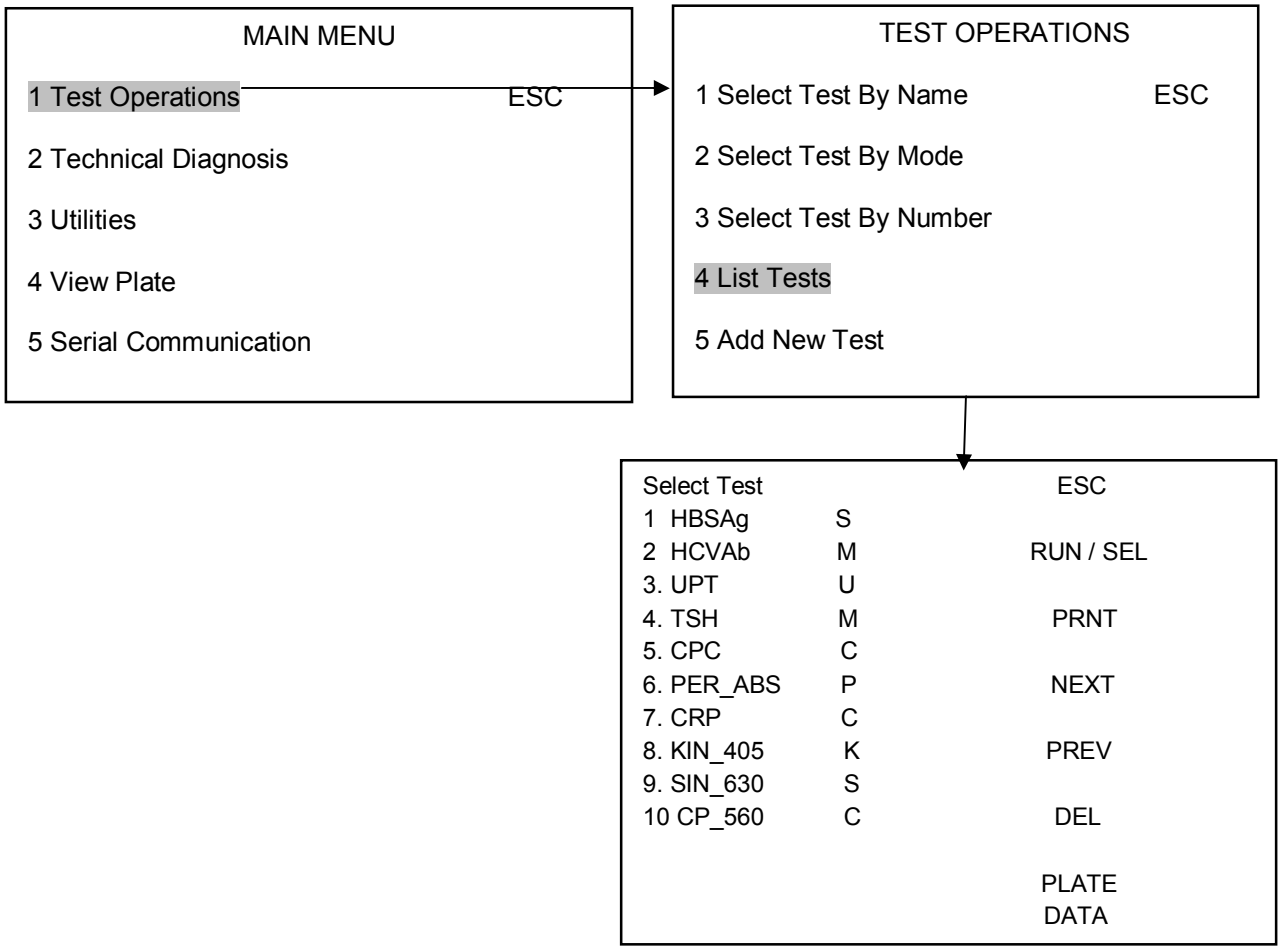
5.3. Keypad

1) 'YES' key is used to select any 'YES' option on screen directly.
2) 'NO' key is used to select any 'NO' option on screen directly.
3) 'PRINT' key is used to get a printout of current screen displayed.
4) 'TEST' key is used for directly accessing the RUN screen of the selected test.
5) Navigation keys are used to select any option available on current screen.
6) 'ENTER' key is used to run any option selected by navigation keys.
7) 'ESC' key is used for escaping from any screen.
8) 'SHAKE' key is used for directly accessing the shaking mode (ie. SHAKER) (refer 15.5 for more details on SHAKER)

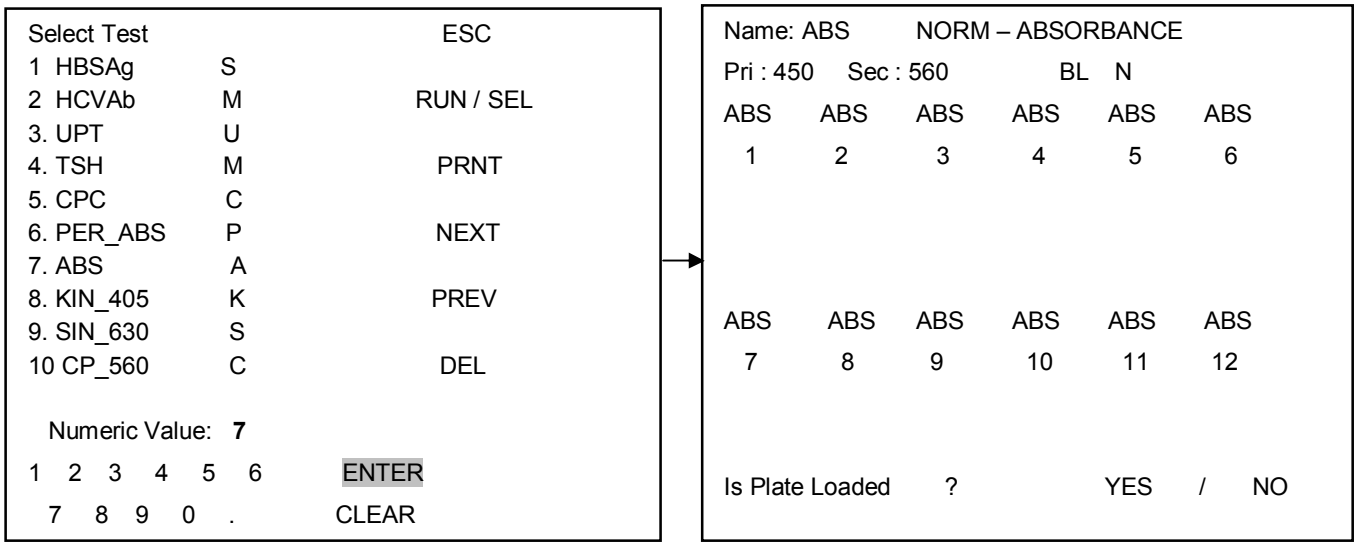
(Note: Functions based on HOME & FEED keys operates only when it is in List Test screen or the first screen after initializing)


ELISA READER 18/07/12
Clinic name / Serial Number MENU
Select Test
1. HBSAg 6. PER_ABS RUN / SEL
2. HCVAb 7. CRP PRNT
3. UPT 8. KIN_405 NEXT
4. TSH 9. SIN_630 PREV
5. CPC 10. CP_560 DEL
PLATE DATA

User can select "List Test" screen as shown below-



Select "TEST" button present on the keypad. It will display following screen for selecting the particular test. In this way user can directly run the selected test by just entering the valid test no.



6. INSTALLATION PROCEDURE AND VERIFICATION CRITERIA

6.1. Unpacking Instructions

Check accessories as per packing list.

Kindly store all packaging materials so as to use it to repack and ship for maintenance or servicing.

6.2. Placing the Instrument

The instrument has to be placed on a level bench.

Room temperature has to be between 10 to 35ºC with a relative humidity below 85%.

Protect the instrument from direct sunshine.

6.3. Power Supply Requirements

Plug the instrument into a power source by the locally available approved plug in cable.

Power cord should be CE, CSA, and UL marked.

115 - 230 Volt ± 10%, 50-60 Hz

6.4. Protective Grounding

Please make sure that electrical power source is properly grounded.

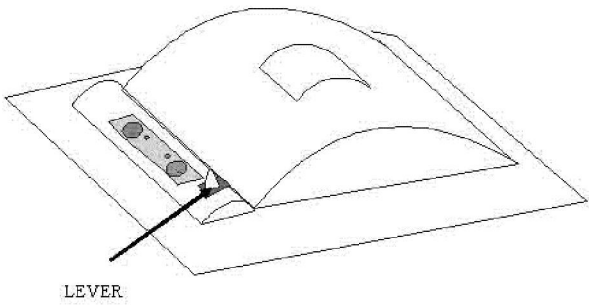
6.5. Printer

ELISA READER Analyser is equipped with a built in 52 columns easy load thermal printer. Procedure to load the paper is as follows:

Opening the Paper Cover:

Slide the LEVER towards back of the printer to open lock of the Paper Cover.

Lightly push up on the front of the paper cover (marked) with your thumb and rotate it towards the back of the printer.



Closing the Paper Cover + replacement of paper roller:

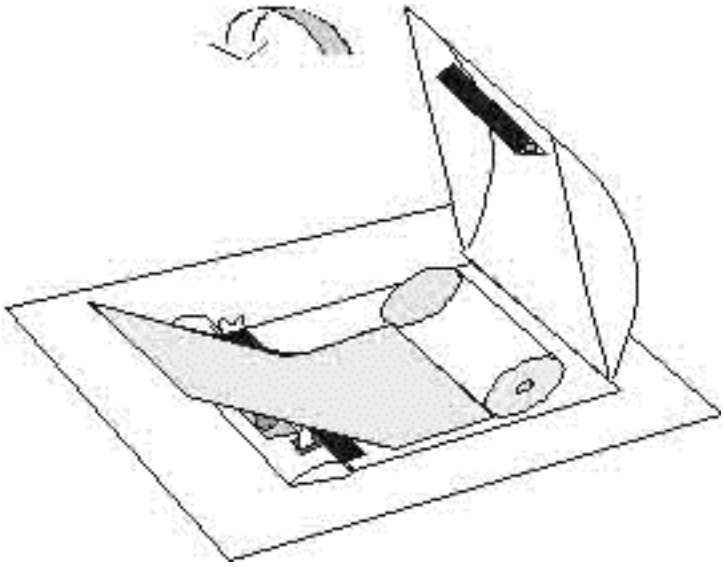
Close the paper cover and push down till you get locking sound.

Open the paper cover.

Remove the paper roller from the slot and place the paper roll over it as shown.

Place back the paper roller with paper into the slot provided and close the paper cover as described before.

Keep pressing the paper feed switch until the paper feeds straight and smoothly.



HINT:

When the paper is set correctly and when the closing of the paper cover is proper the FEED LED will not glow.

It keeps on flashing when the data is being printed.

When the paper is almost finished, red lines appear on both sides of the paper.

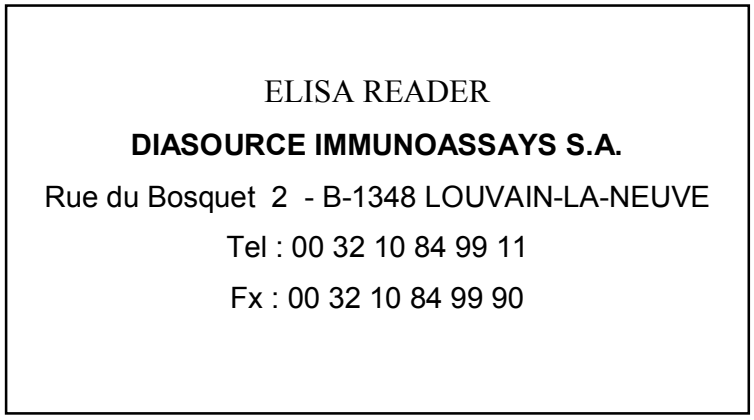
6.6. Start up Instructions

Switch on the instrument.

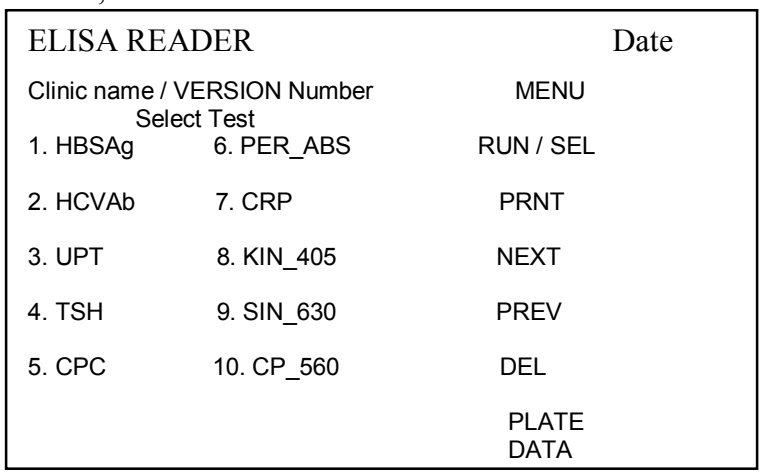
The instrument initializes all the parameters internally and carries out a power on self-test

During Initializing it displays the string: “Please wait system initializing.”

It will display the ADDRESS screen after completing the initialization.



The instrument will print the model name “ELISA READER”, VERSION NUMBER, CLINIC NAME, CURRENT DATE WITH TIME.



User can select a saved test by first touching the required “Test Name” on the screen and then touch the “SEL” option to carry out further operation on the test.

“RUN” option is used to directly run the selected test.

“DEL”: Deletes the selected test.

If the numbers of tests are more than 10, “NEXT” and “PREV” options can be used for browsing through the list pages.

“PRINT”: For printing the test screen.

“MENU” used to select Main menu screen.

"PLATE DATA” this option helps the user to view the Plate Results easily by selecting this option present on the screen.

6.7. Touch Panel Check

ELISA READER provides a ***Touch sensitive LCD panel*** **and a** ***KEYPAD*** for easy use interface**.**

The Menus are displayed and the text of the parameter forms the TOUCH ZONE.

Touch screen Layout

Name:			POS- CutOff			
Pri: 405	Sec: 0					ESC
						EDIT
No	Factor	QC	QCVal	Mes.	Rem	RUN
BL 0		N				
NC 0	1.000	N				
PC 0	1.000	N				
LC 0	1.000	N				
CC 0	1.000	N				
CUTFAC: 0.000						
CUTABS:						
QC1N			Interpretation :			
QC2N			Greyzone % (N)			
QC3N			Cut off Index (Y)			
QC4N			Range	Pos : 0.000		
				Neg : 0.000		

Above is the generic representation of a Test Screen. The Highlighted zones are TOUCH ZONES, which are active. On touching the “Touch Zone” of a parameter, a sub menu/menu is displayed or the requested action is carried out. The rest of the “Touch Zone” is deactivated.

For Example: To activate the selection:

Enter the primary filter value to touch any point in the shaded area “Pri” on the LCD screen.

On proper selection the analyser responds with blinking of the parameter text and also the TOUCH ZONE and a submenu is displayed.

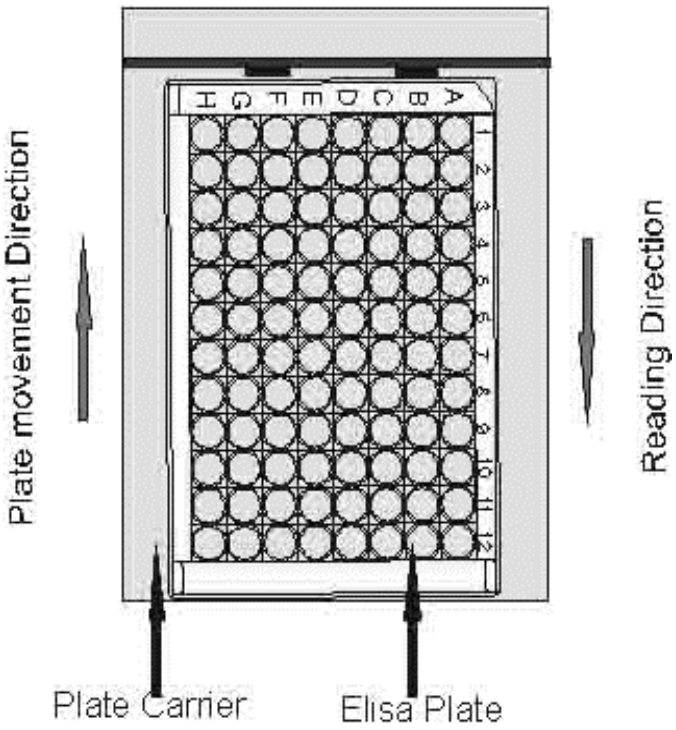
To enter Test Name: Touching the “Name” touch zone provides an alphanumeric screen.

Enter the Test name by touching the Touch zone of that variable. The selected value blinks and is displayed next to the parameter.

Selection Indicator

Selected on screen item is shown in a shaded background. When the screen first displays, the default selection is shown. Pressing a selection either highlights that item or activates it.

6.8. Micro Titer Plate Carriage



The instrument is provided with a micro titer plate carriage to move the micro titer plate inside. This carriage is driven by stepper motor with timing belt. It places each well of plate exactly below the optical path of each channel. The plate carrier is moved by a well controlled stepper motor drive.

6.9. Plate Loading & Pipetting Procedure

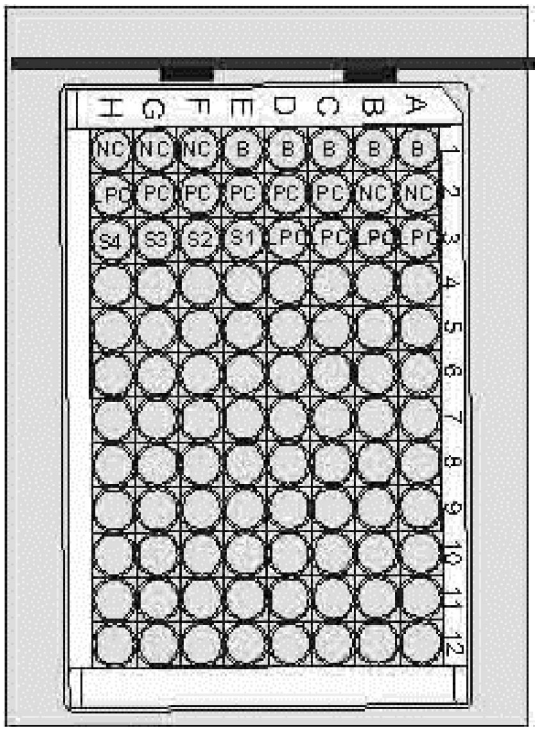
Control and sample pipetting procedure in case of cut off:

Maximum number of Blanks = 5

Maximum number of Controls:

1. Negative Control = 05
2. Positive Control = 05
3. Cut of control = 05
4. Low Positive Control = 05

Pipetting sequence should be as shown below.



6.10. Readings Check

Checking of readings should be done through controls reading within range specified in data sheet of controls (care should be taken while preparing and pipetting controls and reagents, reagent and control expiry dates need to be checked).

7. PRECAUTIONS

Do not use any sharp objects on the Touch Screen. Always use the STYLUS provided to operate the touch panel.

Always check for proper grounding before installation. Never operate the instrument when ground wire is removed.

3. Do not attempt to open the instrument and make repairs without proper technical training. Do not allow unauthorized persons to operate or repair the instrument.

4. Use a clean plate and follow the instructions for blanking and standardizing. Do not read any wells containing bubbles or dust particles.

5. The volume of sample, calibrators and blanks should be identical for correct readings. The absorbance is proportionate to the path length. Pipetting should also be proper.

6. Monitoring of the printed values or displayed values during operation may help detect an error. Check the linearity and calibration of the instrument regularly against some standard reference.

7. Check the micro wells before use. They should be scratch-free. The micro well track in the **ELISA READER** has been designed in such a way that the micro wells are totally protected from scratches.

Recheck the reading of high OD (above 2A).

9. Place Plate carefully on the tray.
10. Ensure that the main power switch is in OFF position before connecting.
11. Plug the instrument to the AC mains. Confirm proper grounding for trouble free operation.
12. Connect the printer only when the instrument is OFF.

8. PROGRAMMING MODES

We would like to highlight that the assay protocols reported in this section correspond to illustrations. When programming the instrument, the end-user must always refer to the instruction for use specific to each assay.

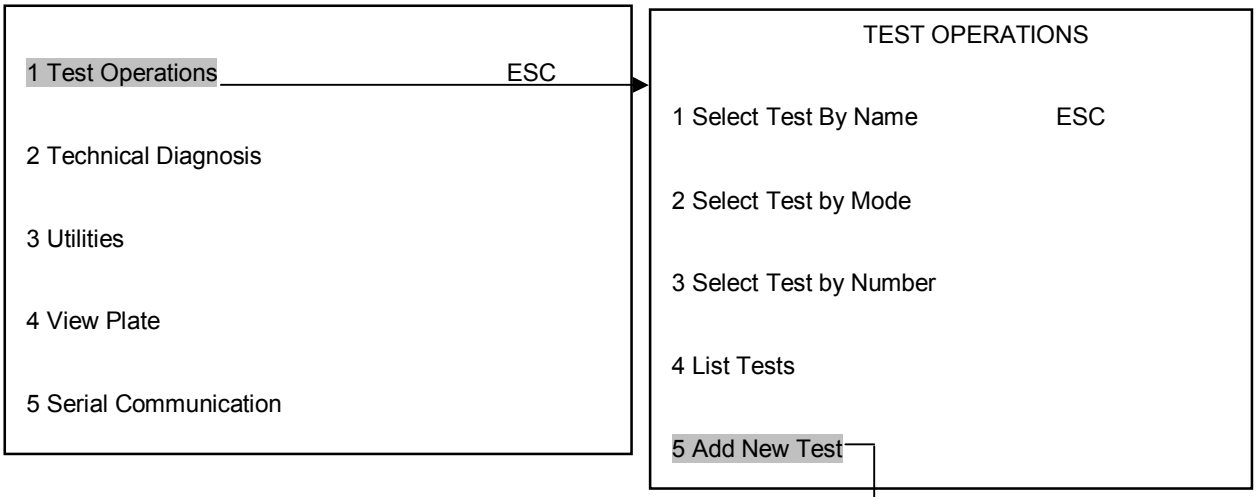
8.1. Absorbance Mode

In this mode the instrument gives only absorbance of all wells of plates of the respective plate.

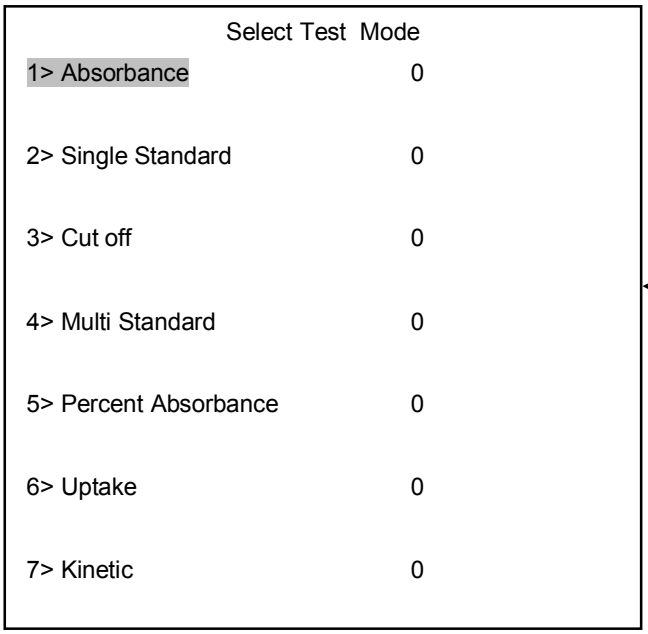
Programming a New Test:

A. Select "Test Operation"

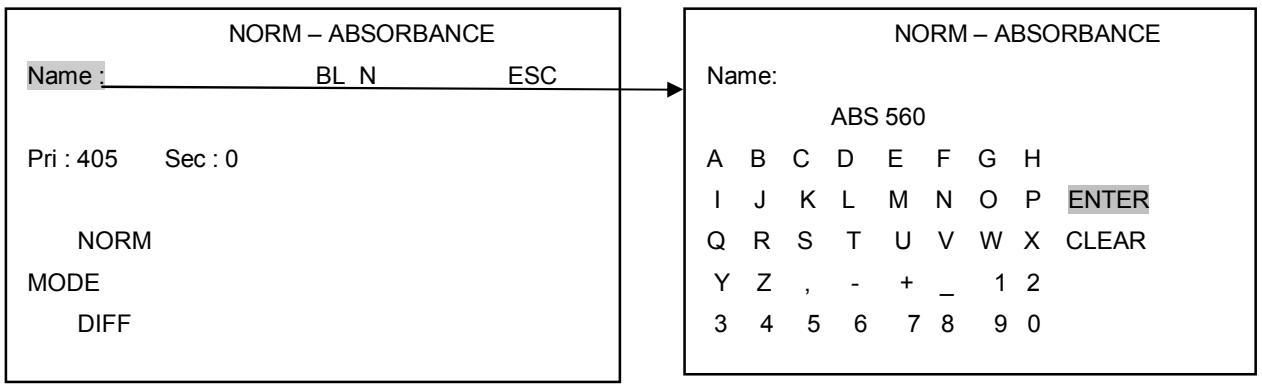
B. Select "Add New Test"



C. Select mode of operation "Absorbance" in "Add new test"

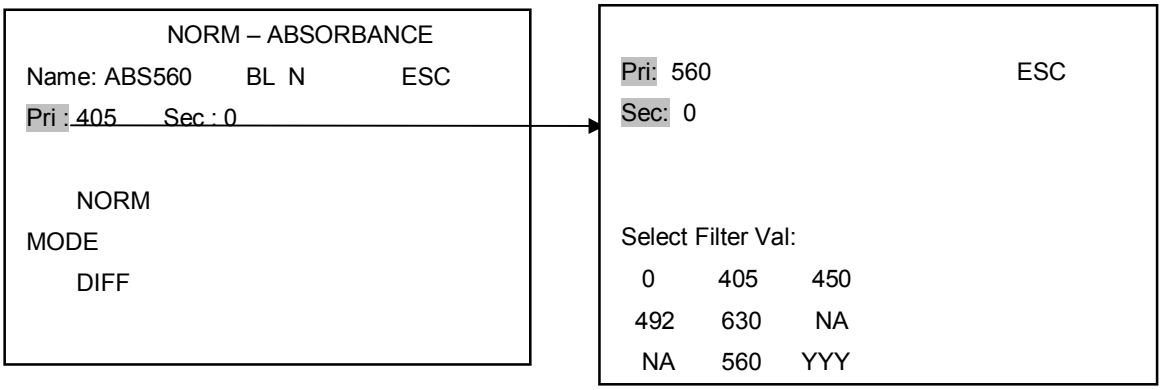


D. Enter "Test Name"

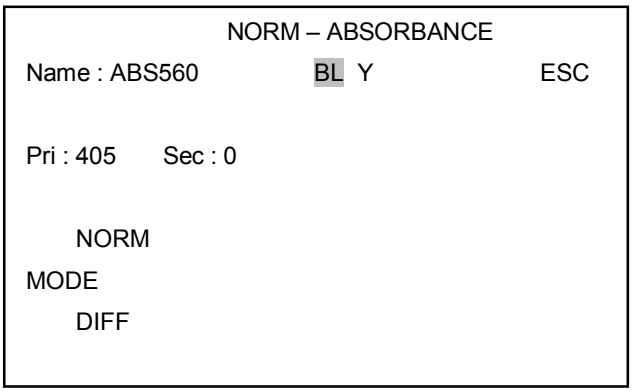

NORM – ABSORBANCE
Name : BL N ESC
Pri : 405 Sec : 0
NORM
MODE
DIFF
NORM – ABSORBANCE
Name:
ABS 560
A B C D E F G H
I J K L M N O P ENTER
Q R S T U V W X CLEAR
Y Z , - + _ 1 2
3 4 5 6 7 8 9 0

5. Select primary and secondary filter

E. Select primary and secondary filter



F. If blank is required select ”BL”



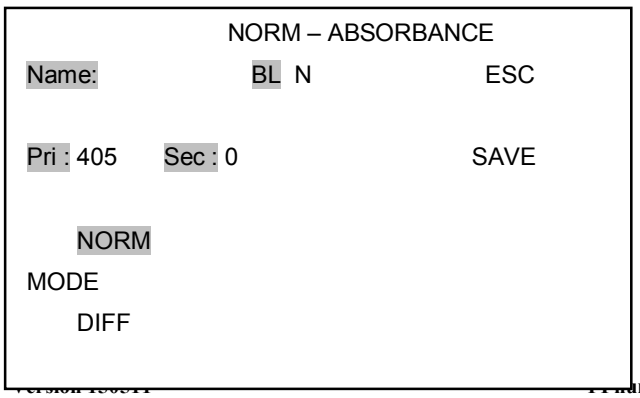
If you select “BL Y”, it will read first well first strip ‘A1’ as a blank and subtract the absorbance of blank well from all other well’s absorbance.

G. In absorbance mode there are two modes of operations

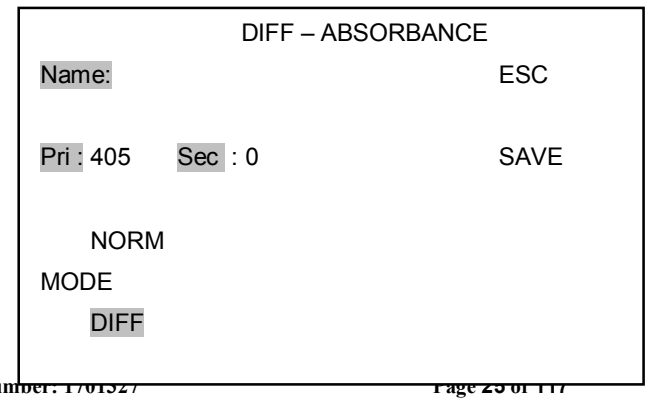
Normal Absorbance Mode: Instrument gives the absorbance of each and every well.
Select touch zone “NORM”.

Differential Absorbance Mode: Instrument shows the difference of absorbance between odd number wells and even number wells. For Example,- Strip 1,- Strip 2, - Strip 3, - Strip 4, - Strip 5, -Strip 6. For this Mode select touch zone “DIFF”.

In Normal Mode



In Differential Mode



8.2. Single Standard

In this mode the instrument accepts the calibrator singly or in duplicate and then calculates the concentration based on the single point standard curve passing through the point 0.000

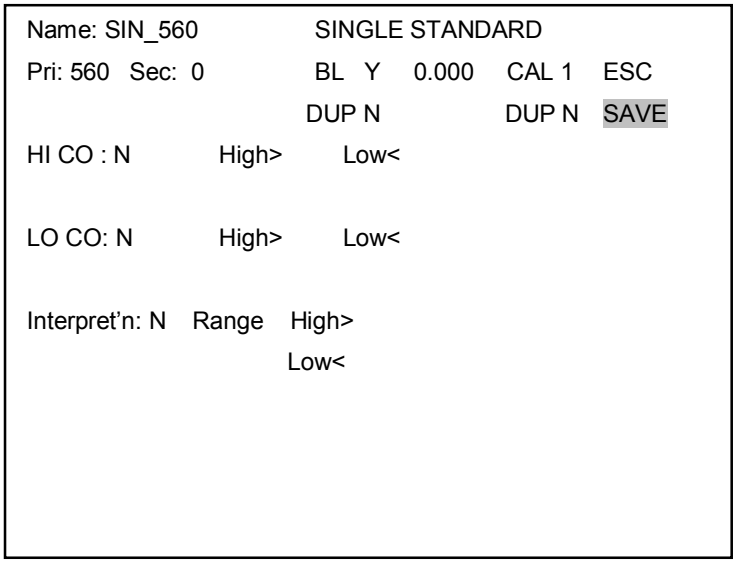
A single calibrator/standard of a known concentration is used to calibrate the instrument so that the concentration of unknown samples can be calculated according to Beer's Law. The absorbance are read at user selected wavelengths. If Blank is selected, instrument will automatically blank on the first well and subtract its absorbance from each subsequent well. The second well is treated as the calibrator/standard well. The third well is also treated as calibrator/standard well if the calibrator/standard is in duplicate.

CALCULATION:

Sample Concentration = (Calibrator concentration /Calibrator Abs.) x Sample Abs

CALCULATION:

Sample Concentration = (Calibrator concentration /Calibrator Abs.) x Sample Abs



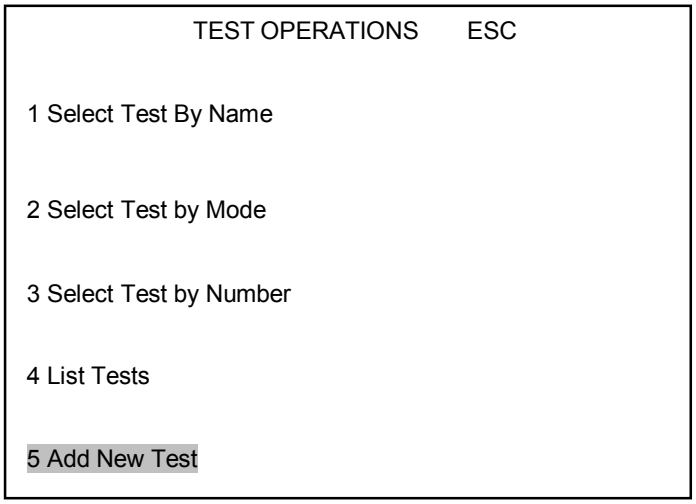
Entry of all the parameters is similar to Multi standard mode (Please refer Multi standard for entry of parameters)

8.3. Cut Off Mode

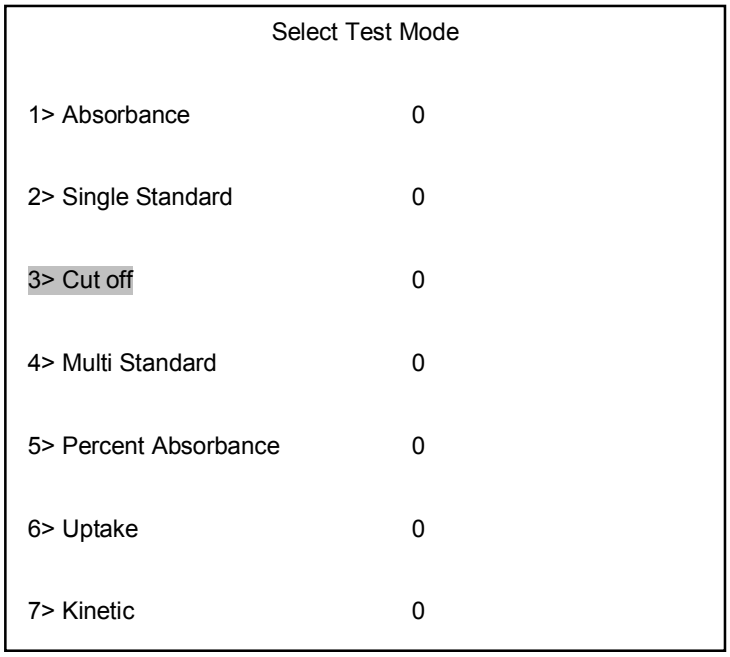
In this mode cut-off point is determined for interpretation of specimens as per formula given in the reagent manual. The negative controls are read followed by the positive controls, Cut-off control, low positive control. Blanking on the first well is optional. The instrument calculates the average of the negative controls and the average of the positive control, Cut-off controls and Low positives are also calculated.

Programming a New Test:

A. Select "Add New Test"



B. Select mode of operation "Cut-Off" in "Add new test"



C. Entry of test name

Select touch Zone "Name:"

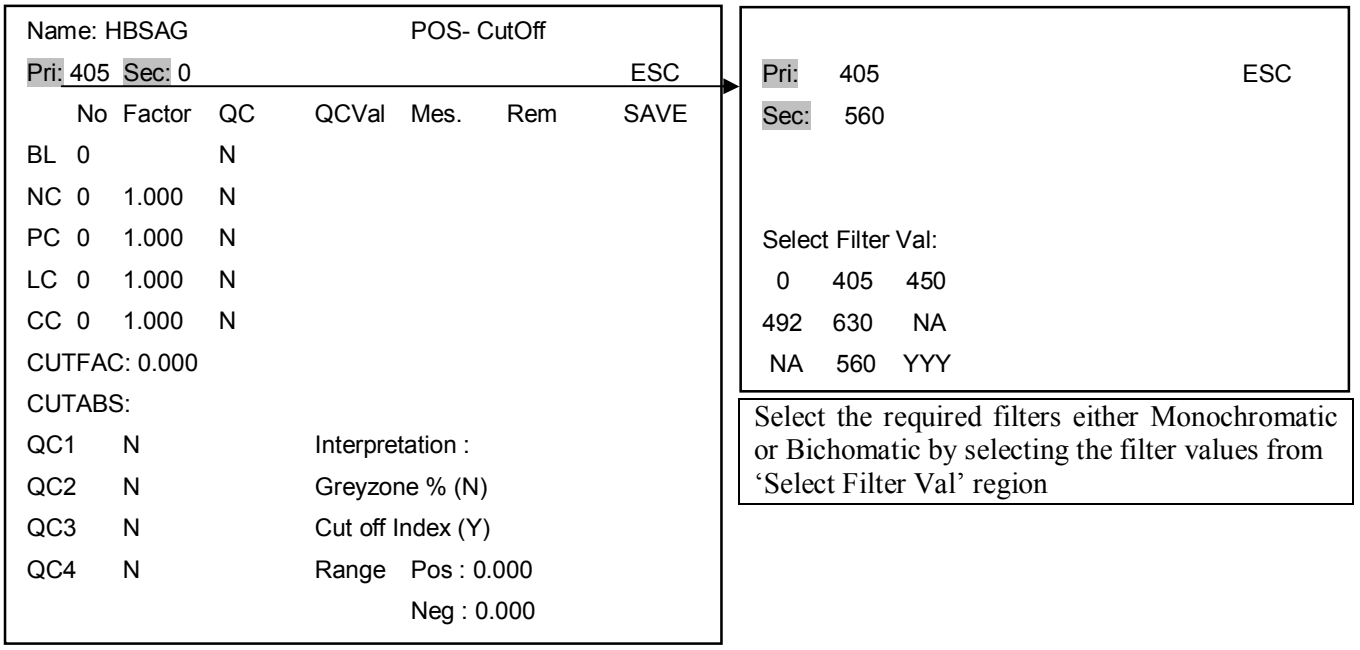
Name:				POS- CutOff			
Pri: 450	Sec: 0						ESC
	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	0		N				
NC	0	1.000	N				
PC	0	1.000	N				
LC	0	1.000	N				
CC	0	1.000	N				
CUTFAC: 0.000							
CUTABS:							
QC1N				Interpretation :			
QC2N				Greyzone % (N)			
QC3N				Cut off Index (Y)			
QC4N				Range	Pos : 0.000		
					Neg : 0.000		

Alphanumerical characters will appears on the screen as shown below after touching "Name" on the screen. Enter the name of the test by selecting the individual characters one by one. After selecting all the characters select Enter option in touch screen for confirmation of test Name.

Name:					POS- CutOff			
			HBSAG					
A	B	C	D	E	F	G	H	
I	J	K	L	M	N	O	P	ENTER
Q	R	S	T	U	V	W	X	CLEAR
Y	Z	,	-	+	_	1	2	
3	4	5	6	7	8	9	0	

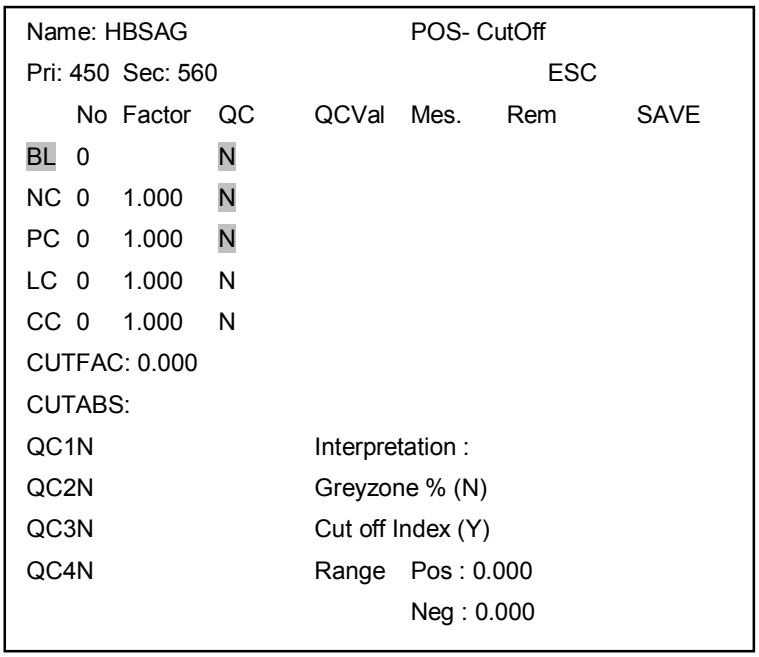
D. Selection of Primary and secondary filters.

Select zone "Pri:" on the touch screen



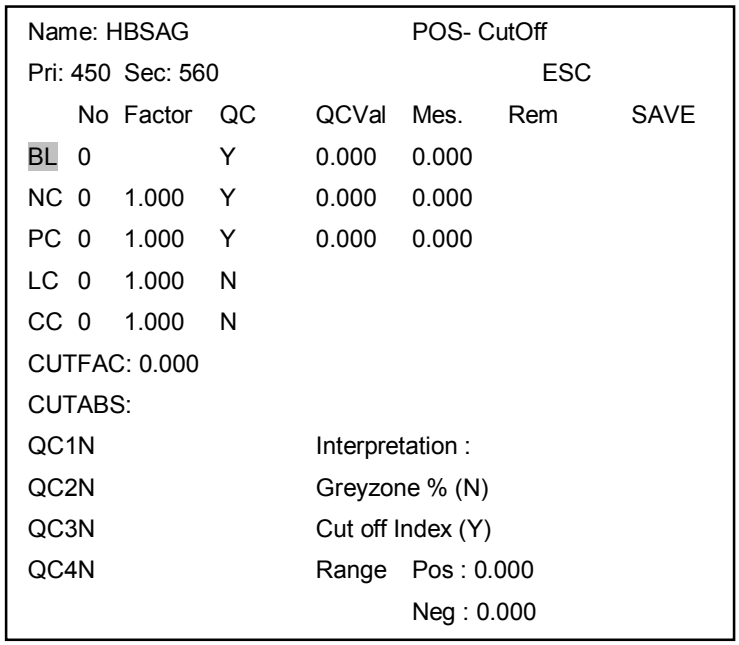
Select the required filters either Monochromatic or Bichomatic by selecting the filter values from 'Select Filter Val' region

E. According to the reagent manual change Blank, NCs, PCs to 'YES' for QC check.

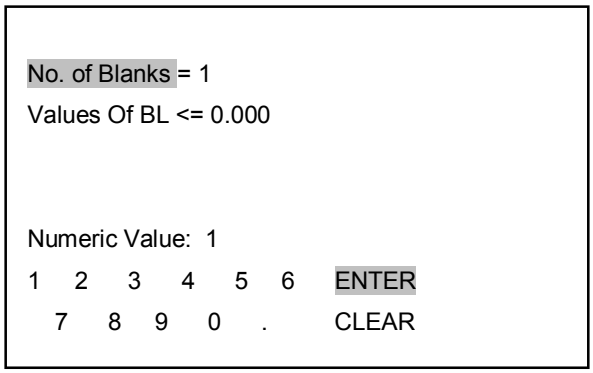


F. Entry of Blank and Blank QC values

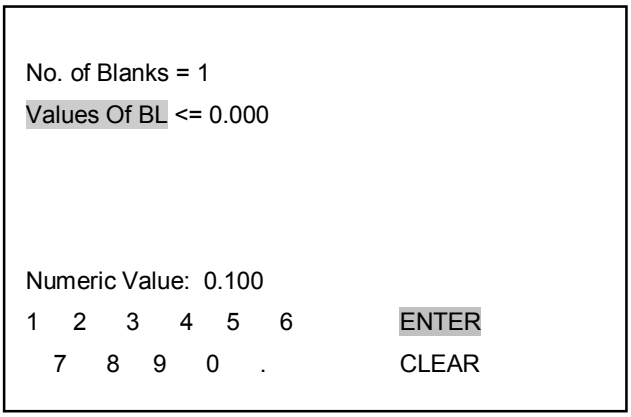
Select "BL" to enter blank details.



G. After selecting "BL", enter total number of blanks by selecting No. of Blanks. (Maximum 5 blank).

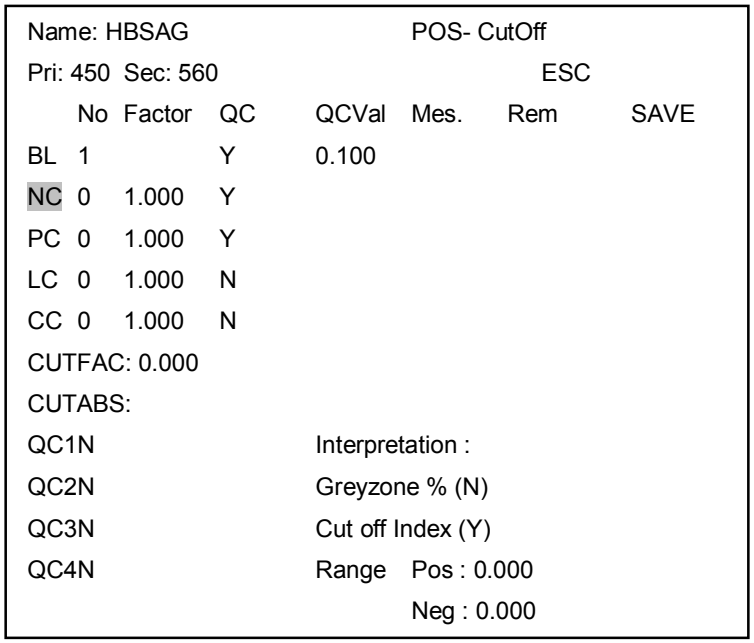


H. Enter the QC value of the blank by selecting the touch Zone "Values of BL <="

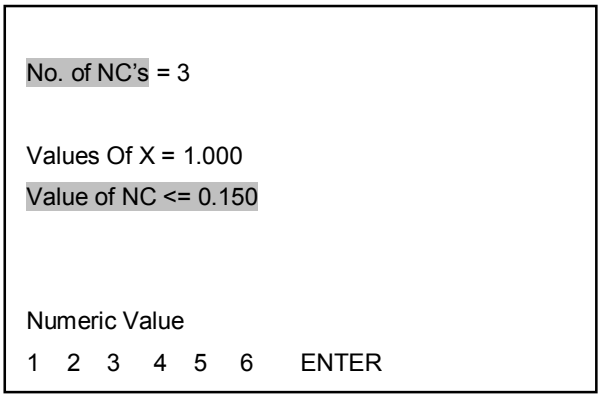


I. Entry of Negative control and its QC values

Select touch Zone "NC"



Enter N° of Negative controls by selecting touch Zone "N°of NC's" (maximum 5 Negative Controls). Enter the QC value of the Negative Control by selecting the touch Zone "Value of NC" and enter the value of X given in the reagent manual by selecting Zone "Values Of X".



K. After the entry of N° of NC's Select ESC. The below screen will appear on the display.

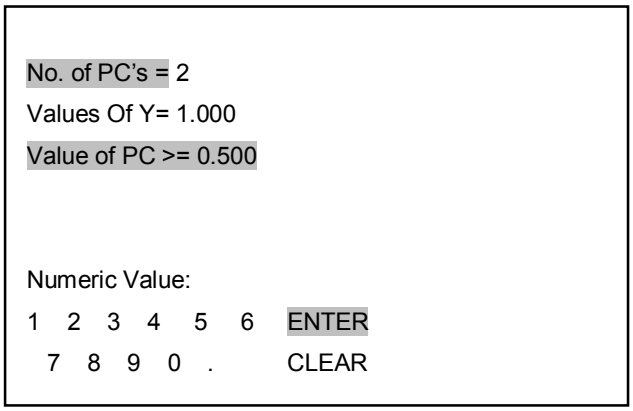
Name: HBSAG				POS- CutOff			
Pri: 450	Sec: 560					ESC	
	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	1		Y	0.100			
NC	3	1.000	Y	0.150			
PC	0	1.000	Y				
LC	0	1.000	N				
CC	0	1.000	N				
CUTFAC: 0.000							
CUTABS:							
QC1N				Interpretation :			
QC2N				Greyzone % (N)			
QC3N				Cut off Index (Y)			
QC4N				Range	Pos : 0.000		
					Neg : 0.000		

L. Entry of Positive Controls (PC).

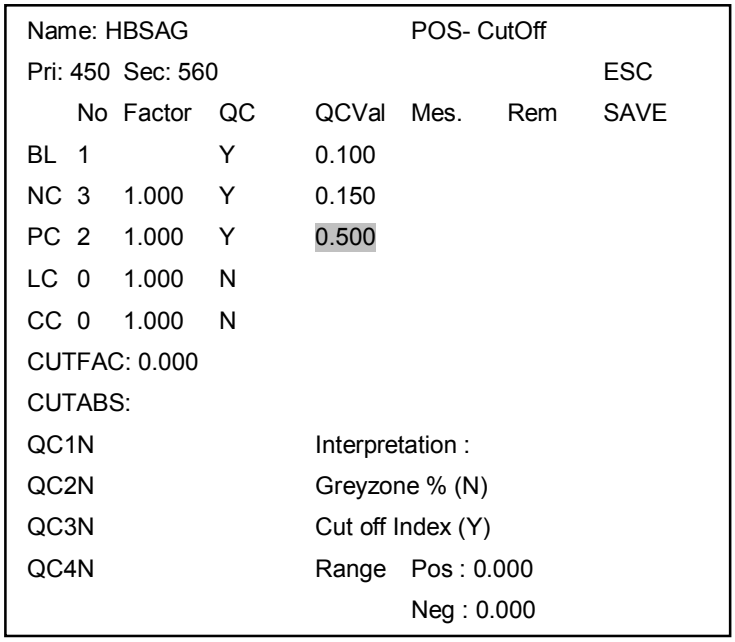
Select touch Zone "PC".

Name: HBSAG				POS- CutOff			
Pri: 450	Sec: 630					ESC	
	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	1		Y	0.100			
NC	3	1.000	Y	0.150			
PC	0	1.000	Y				
LC	0	1.000	N				
CC	0	1.000	N				
CUTFAC: 0.000							
CUTABS:							
QC1N				Interpretation :			
QC2N				Greyzone % (N)			
QC3N				Cut off Index (Y)			
QC4N				Range	Pos : 0.000		
					Neg : 0.000		

M. After selecting No. of PC's the screen below will appear on the display. Enter number of Positive Controls by Selecting Zone "No. of PC's" (Maximum 5). Enter the QC value of the Positive Control by selecting the touch Zone "Value of PC >=" and enter the value of Y given in the reagent manual by selecting Zone "Values Of Y".



N. After entering the details of PCs, escape from the screen by selecting "ESC". Below screen will appear on the display:



NOTE: Same way you can enter values for LC (lower positive controls) and CC (Cut of Controls).

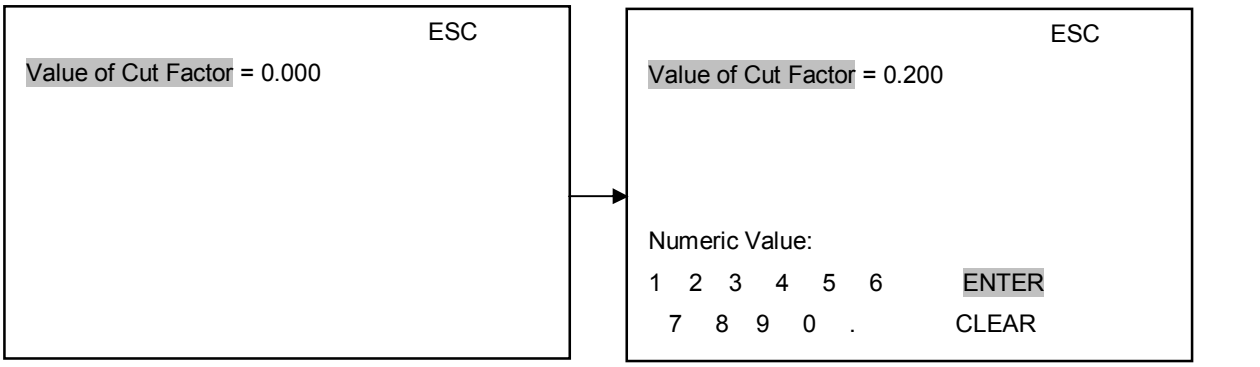
O. Entry of Cut off Factor:

Select touch Zone "CUT FAC"

Name: HBSAG				POS- CutOff			
Pri: 450	Sec: 560						ESC
	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	1		Y	0.100			
NC	3	1.000	Y	0.150			
PC	2	1.000	Y	0.500			
LC	0	1.000	N				
CC	0	1.000	N				
CUTFAC: 0.000							
CUTABS:							
QC1N				Interpretation :			
QC2N				Greyzone % (N)			
QC3N				Cut off Index (Y)			
QC4N				Range	Pos : 0.000		
					Neg : 0.000		

After selecting the "CUTFAC" following screen will come on the display:

After selecting the "CUTFAC", it will display following screen.



Enter the Value for Cut Off Factor and select ESC option to come out to the test parameter screen.

P. Entry of Cut off absorbance equation:

Select touch Zone "CUTABS"

Name: HBSAG				POS- CutOff		
Pri: 450	Sec: 560					ESC
	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	1		Y	0.100			
NC	3	1.000	Y	0.150			
PC	2	1.000	Y	0.500			
LC	0	1.000	N				
CC	0	1.000	N				
CUTFAC: 0.200							
CUTABS:							
QC1N				Interpretation :			
QC2N				Greyzone % (N)			
QC3N				Cut off Index (Y)			
QC4N				Range	Pos : 0.000		
					Neg : 0.000		

After selecting the "CUTABS" below screen will come on the display.

CUTABS:						ESC
CUT ABS = **NC + PC + CF**						
NC	PC	LC	CC	CF		ENTER
+	-	,	*	%		CLEAR
1	2	3	4	5	6	
7	8	9	0	.		
(					)	
Sqrt Lg	ALg	Ln	ALn	Abs		

For entering the CUTABS equation, user has to select CUTABS present on the screen.

Now enter the equation as given in the reagent manual or else select ESC option in order to come out of the CUTABS screen.

Whereas, NC = Mean of NCs * Factor X

PC = Mean of PCs * Factor Y

LC = Mean of LCs * Factor W

CC = Mean of CCs * Factor Z

CF = Cut off Factor

Sqrt = Square root

Lg = LOG

Aln = Anti Natural LOG

Ln = Natural LOG

Abs. = any absolute value

ALg = Anti LOG

For Example :

For equation CUT OFF ABS = (0.45 * NC) + (0.35 * PC) + 0.10, the formula can be entered in two ways.

1. Enter the values as it is i.e. CUTABS = (0.45*NC) + (0.35*PC) + 0.010. Keep the multiplication factors X, Y, W, Z of controls NC, PC, CC and LC a constant number '01'. (Numbers, mathematical functions and symbols for NC, PC, CC, LPC can be selected from the screen).

OR

2. In second method the formula can be entered as CUT ABS = NC + PC + CF. (Since the Value of X, Y, Z, W is entered in the QC option of NC, PC, CC, LPC and Cut off factor in the CUT FAC option, there is no need to enter the same data again). Means here Multiplication Factor for NC = X = 0.45

Multiplication factor for PC = Y = 0.35 and the value of cut of factor = CUT FAC = 0.100.

This is because here NC = Mean of NCs * Factor X, PC = Mean of PCs * Factor Y as mentioned above.

If 'CUTOFF ABS' = (NC + PC) / 6. This can be entered as it is CUTABS = (NC + PC) / 6 by keeping the multiplication factors X, Y, W, Z of controls NC, PC, CC and LC a constant number '01'.

OR

As you know in mathematics (NC + PC) / 6 = (NC / 6) + (PC / 6) =
(1/6) * NC + (1/6) * PC = (0.166 * NC) + (0.166 * PC),

So, you can enter same equation as CUT ABS = NC + PC, by entering

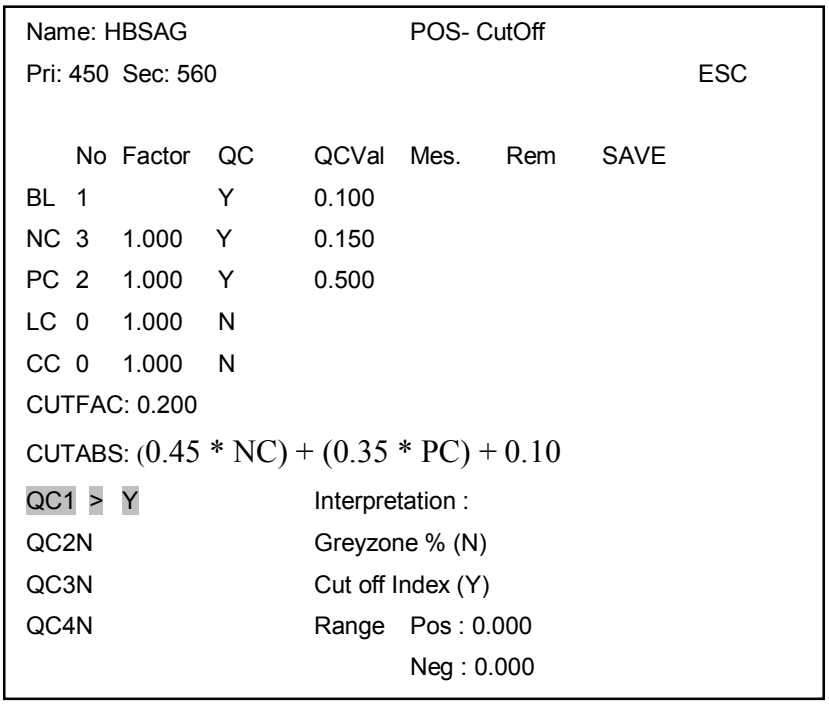
Multiplication Factor for NC = X = 0.166, multiplication factor for PC = Y = 0.166.

This is because here NC = Mean of NCs * Factor X, PC = Mean of PCs * Factor Y as mention above.

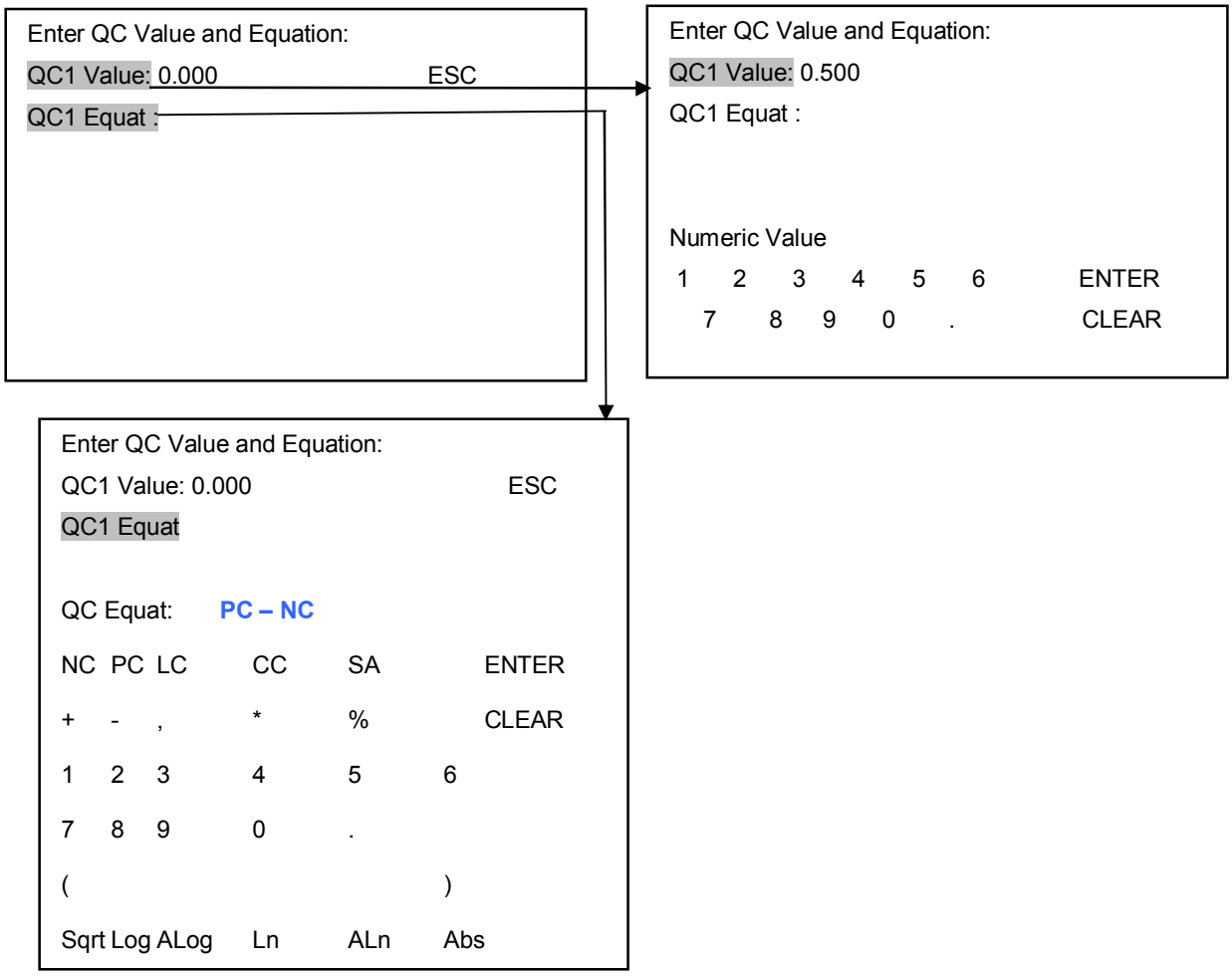
Q. QC1, QC2, QC3 & QC4. can be used for any QC Checking of the test provided in reagent manual.

For example some kit may give QC check equation like| PCx – NCx |> 0.500,

PC / NC > 15, etc. This equation can be entered by selecting these QC options. Select touch zone 'N'. You will obtain 'Y', as shown in screen below by selecting touch zone 'QC1' and entering QC equation.



Enter equation of QC and value of QC check by selecting touch zone 'QC1 Value' and 'QC1 equat'.


Enter QC Value and Equation:
QC1 Value: 0.000 ESC
QC1 Equat :
Enter QC Value and Equation:
QC1 Value: 0.500
QC1 Equat :
Numeric Value
1 2 3 4 5 6 ENTER
7 8 9 0 . CLEAR
Enter QC Value and Equation:
QC1 Value: 0.000 ESC
QC1 Equat
QC Equat: PC – NC
NC PC LC CC SA ENTER
+ - , * % CLEAR
1 2 3 4 5 6
7 8 9 0 .
( )
Sqrt Log ALog Ln ALn Abs

Same way you can enter QC equations for QC2, QC3 and QC4.

***NOTE:**

On screen it is mentioned that "QC1 > Y". In most of the reagent inserts it is mentioned that QC value should be greater than some constant value. Sometimes in the box insert it is mentioned that the value should be less than some constant value. In such case, you can change the symbol from "QC1 > Y" to "QC1 < Y", only by selecting a symbol of comparison.

If any QC check is selected to 'YES' option, the system will not save the test without entering the QC equation and QC check value of equation.

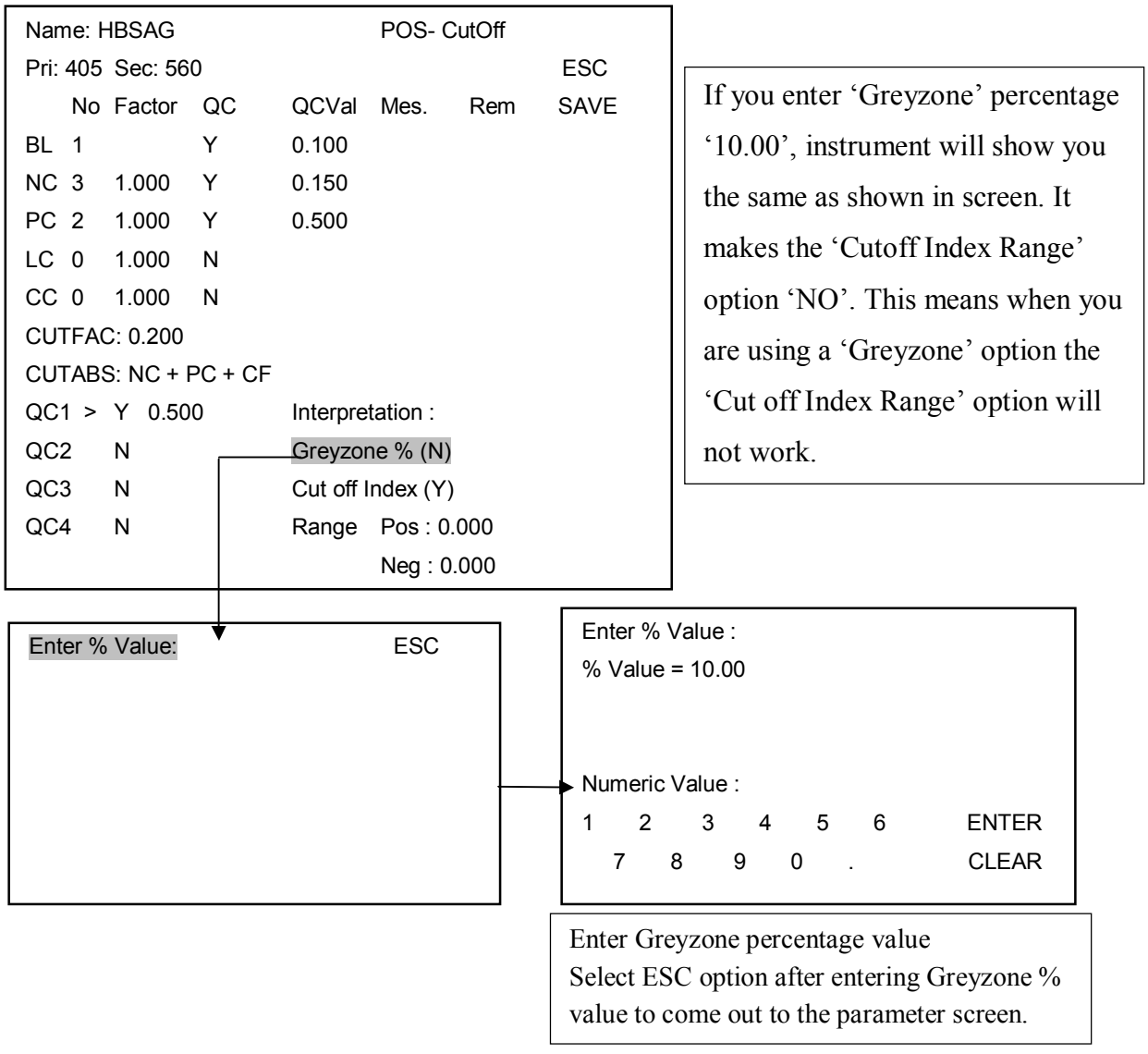
R. Interpretation of samples

Enter RANGE for interpretation of results either in percentage (Greyzone) or positive and negative values of INDEX, as a ratio of (Sample Abs. / Cutoff Abs.). If Cutoff Index range or Greyzone is not mentioned do not enter any values. Instrument will do the interpretation with references to the Cut off absorbance.

R.1. Interpretation by GREYZONE percentage

Select touch zone 'Greyzone % (N)'

Select touch zone 'Greyzone % (N)'


Name: HBSAG POS- CutOff
Pri: 405 Sec: 560 ESC
No Factor QC QCVal Mes. Rem SAVE
BL 1 Y 0.100
NC 3 1.000 Y 0.150
PC 2 1.000 Y 0.500
LC 0 1.000 N
CC 0 1.000 N
CUTFAC: 0.200
CUTABS: NC + PC + CF
QC1 > Y 0.500
QC2 N
QC3 N
QC4 N
Interpretation :
Greyzone % (N)
Cut off Index (Y)
Range Pos : 0.000
Neg : 0.000
If you enter 'Greyzone' percentage '10.00', instrument will show you the same as shown in screen. It makes the 'Cutoff Index Range' option 'NO'. This means when you are using a 'Greyzone' option the 'Cut off Index Range' option will not work.
Enter % Value: ESC
Enter % Value :
% Value = 10.00
Numeric Value :
1 2 3 4 5 6 ENTER
7 8 9 0 . CLEAR
Enter Greyzone percentage value
Select ESC option after entering Greyzone % value to come out to the parameter screen.

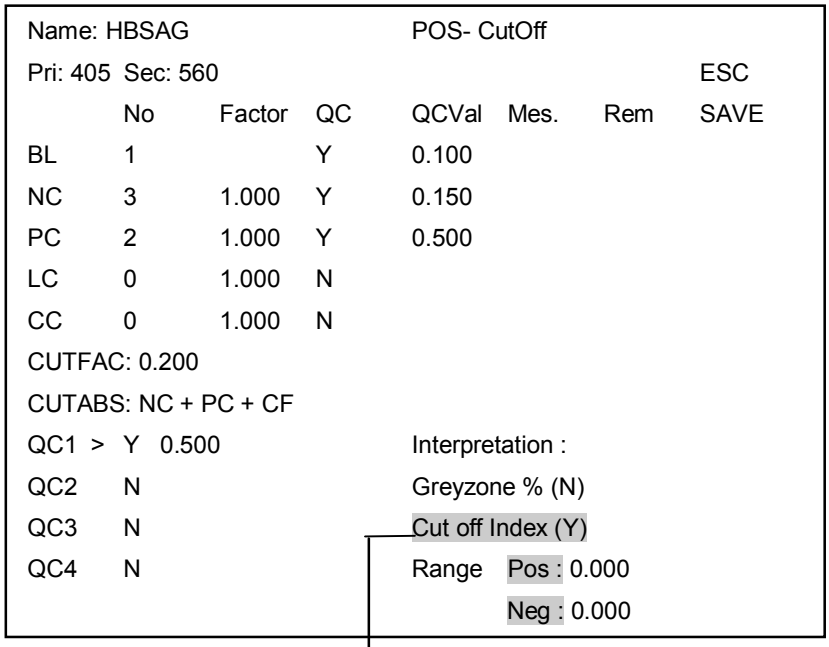
NOTE: If you don't select any option for interpretation of sample results, the instrument will take Cutoff Absorbance as a reference.

It will give "Positive' remark to sample absorbance greater than cutoff and 'Negative' to sample absorbance less than cutoff.

Name: HBSAG				POS- CutOff			
Pri: 450	Sec: 560						ESC
	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	1		Y	0.100			
NC	3	1.000	Y	0.150			
PC	2	1.000	Y	0.500			
LC	0	1.000	N				
CC	0	1.000	N				
CUTFAC: 0.200							
CUTABS: NC + PC + CF							
QC1	>	Y	0.500	Interpretation :			
QC2		N		Greyzone % (Y)	10.00		
QC3		N		Cut off Index (N)			
QC4		N		Range			

R.2. Interpretation by 'Cutoff Index Range"

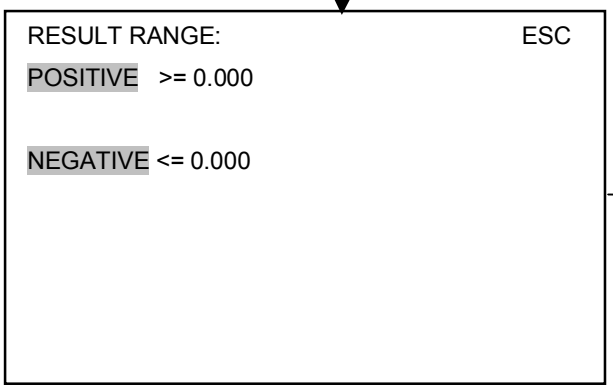
It is also provided to do the interpretation using 'Cutoff Index' by entering normal range for 'Positive' and 'Negative'.

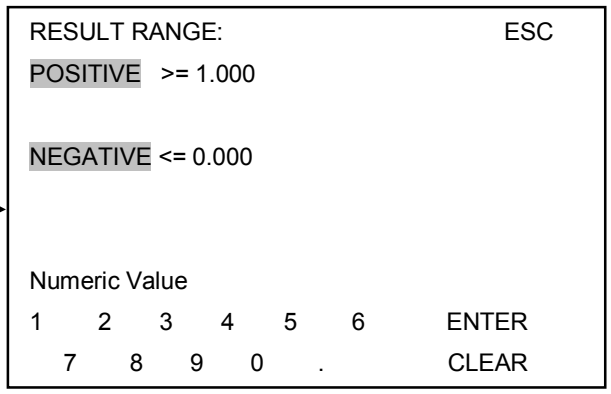


Cut off Index is the ratio of Sample Absorbance / Cut off Absorbance.

When you select 'Cutoff Index' –'Y', the 'Greyzone %' will become 'NO', means inactive.

In 'Cutoff Index', provide the range for interpretation, the positive and negative value of ratio (Sample Abs. / Cutoff Abs.)





In case of 'Cutoff Index Range ',

It gives the 'Positive' remarks to sample having index value, a ratio of …

(Sample abs. / Cutoff Abs.) greater than or equal to entered 'POSITIVE' value and

it gives 'Negative' remarks to sample having index value, a ratio of

(Sample abs. / Cutoff Abs.) less than entered 'NEGATIVE' value.

The sample having index value in between 'POSITIVE' and 'NEGATIVE" range get remarks 'Equivocal' = 'EQ'.

After entering the Interpretation values (ie. conditions for interpretation) the screen will be displayed as follows –

Name: HBSAG			POS- CutOff				
Pri: 405	Sec: 560						ESC
	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	1		Y	0.100			
NC	3	1.000	Y	0.150			
PC	2	1.000	Y	0.500			
LC	0	1.000	N				
CC	0	1.000	N				
CUTFAC: 0.200							
CUTABS: NC + PC + CF							
QC1	>	Y	0.500	Interpretation :			
QC2		N		Greyzone % (N)			
QC3		N		Cut off Index (Y)			
QC4		N		Range	Pos : 1.000		
					Neg : 0.900		

For example:

If you enter POS >= 1.0 and NEG <=0.9.

Then, the sample will get POSITIVE remarks having INDEX Value,

(Sam. Abs./ Cutoff Abs.) >= 1.000.

The sample will get NEGATIVE remarks having INDEX Value,

(Sam. Abs./ Cutoff Abs.) <= 0.900.

The sample will get EQUIVOCAL remarks having INDEX Value,

(Sam. Abs./ Cutoff Abs.) in the range from 0.900 to 1.000.

S. To save the test after entering all the parameters, select 'SAVE' option.

Name: HBSAG			POS- Cut Off				
Pri: 450	Sec: 560						ESC
	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	1		Y	0.100			
NC	3	1.000	Y	0.150			
PC	2	1.000	Y	0.500			
LC	0	1.000	N				
CC	0	1.000	N				
CUTFAC: 0.200							
CUTABS: NC + PC + CF							
QC1	>	Y	0.500	Interpretation :			
QC2		N		Greyzone % (Y)	10.00		
QC3		N		Cut off Index (N)			
QC4		N		Range			

8.4. Reverse Cut Off Mode

For Reverse Cut Off mode, select touch zone 'POS'- Cut off key. It will change to REV- Cut Off.

Name:			REV- CutOff				
Pri: 450	Sec: 0						ESC
	No	Factor	QC	QCVal	Mes.	Rem	SAVE
BL	0		N				
NC	0	1.000	N				
PC	0	1.000	N				
LC	0	1.000	N				
CC	0	1.000	N				
CUTFAC: 0.000							
CUTABS:							
QC1N				Interpretation :			
QC2N				Greyzone % (Y) 10.00			
QC3N				Cut off Index (N)			
QC4N				Range			

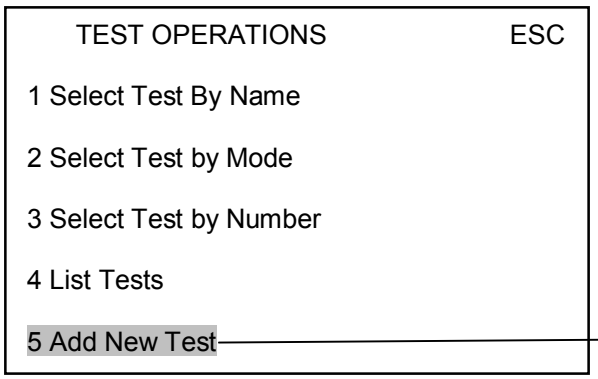
In Reverse Cut Off Mode, programming of test is the same as Positive Cut off Mode. Only QC check conditions for blanks and controls get reversed. In the 'INTERPRETATION', sample absorbance, which is lesser than cut off absorbance, gets remarked POSITIVE . Sample absorbance higher than cut off absorbance, gets remarked NEGATIVE. This is exactly the opposite to normal POSITIVE Cut Off Mode. Same way in case you select 'Cutoff Index Range'.

8.5. Multi Standard Mode:

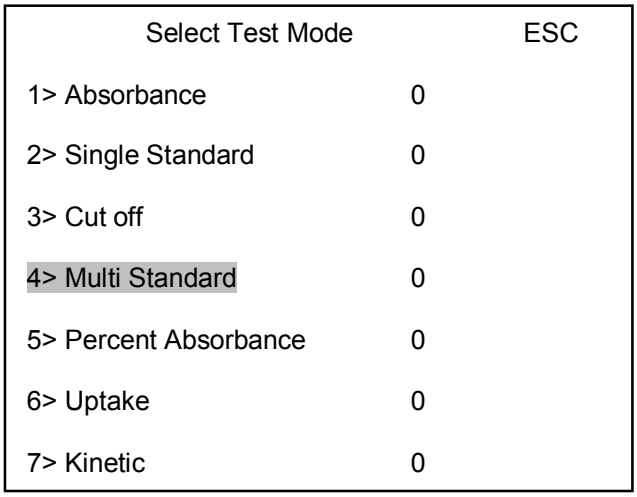
In this mode the instrument accepts a maximum of 12 calibrators and calculates concentration based on the best-fit curve. Graph is printed with Absorbance on Y-axis and concentration on X-axis.

Programming a New Test:

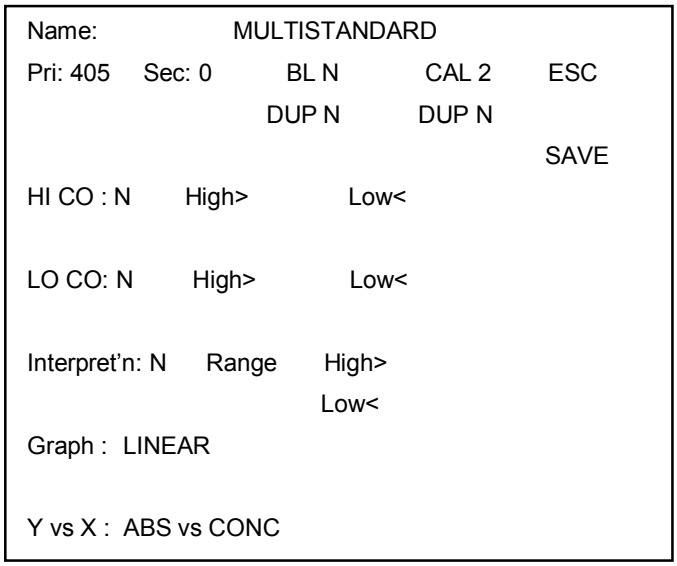
A. Select Main Menu/Test Operation/Add New Test



B. Select Touch Zone "Multi Standard"



After selecting Multistandard mode it will display following screen -



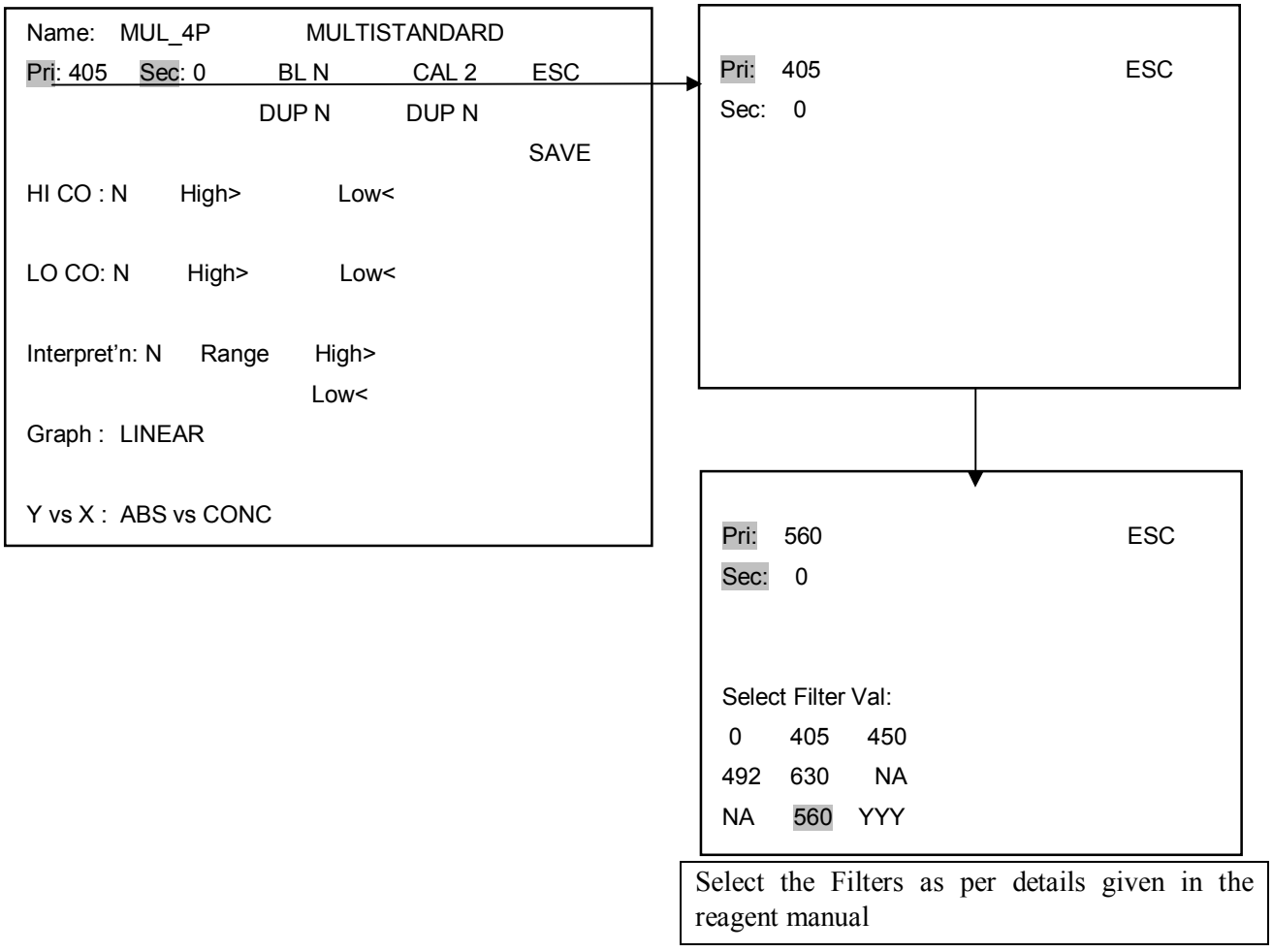
C. Entry of Test Name

Test Name can be entered by Selecting Touch Zone "Name:"

Procedure for entering the test name is the same as the one of cut off mode. Refer Test Name entry in Cut off mode for further details.

D. Selection of Primary and secondary filters

Select Touch Zone "Pri:"

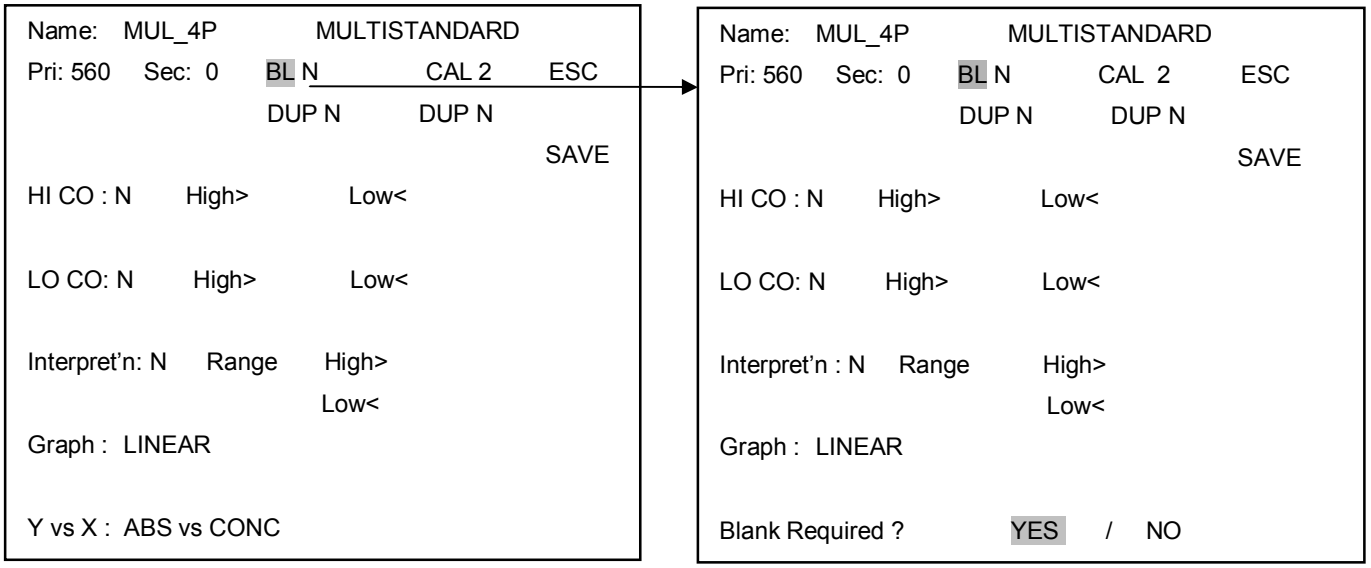


Select the Filters as per details given in the reagent manual

E. Selection of Blank

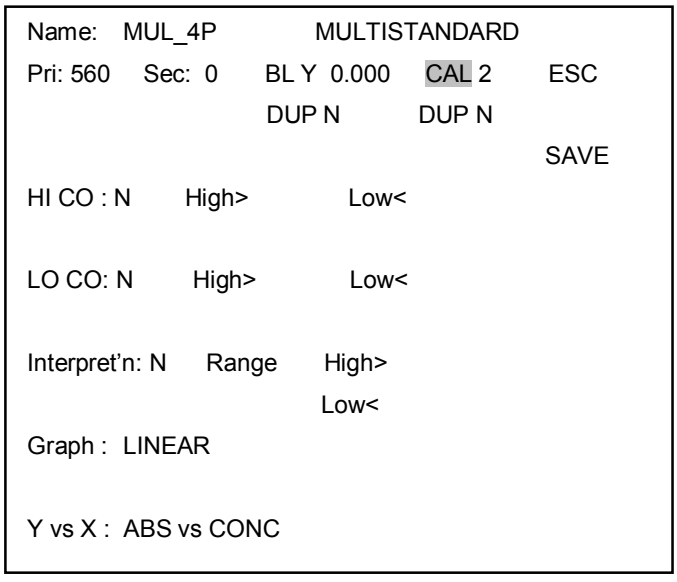
Select Touch Zone "BL"

Select Touch Zone "BL". Instrument will display the message "Blank required Yes/No" at the bottom of the Screen, select "Yes" if blank is required.



F. Entry of Standard Concentration

Select touch Zone "CAL" to enter Number of calibrators and its concentration.

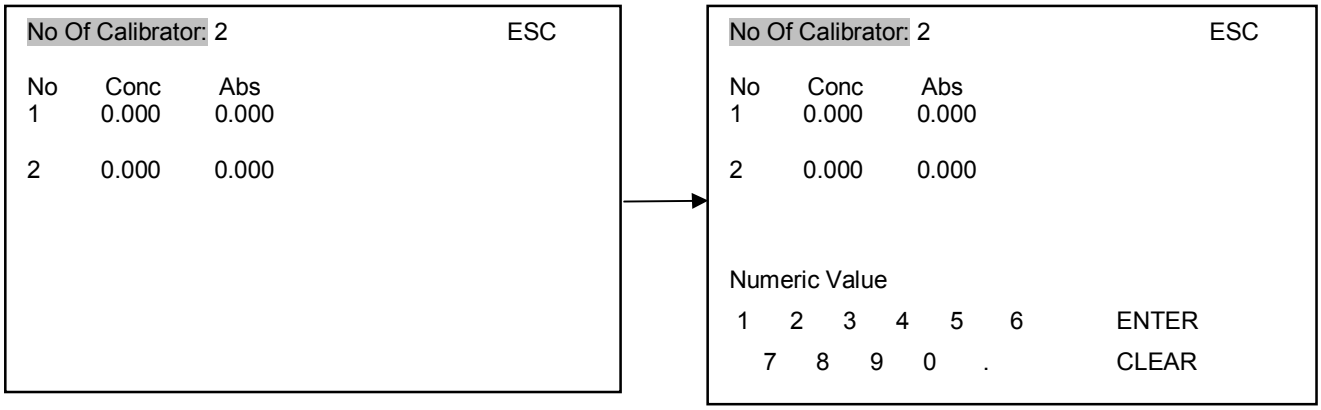


After selecting "CAL", it will display following screen:

Select Touch Zone "No. Of Calibrators". Numeric screen will be displayed at the bottom of the screen.

Select the number of calibrators (User can select min 2 and max. 12 standard in this mode).

Whereas in case of 4 Parameter, user can select min. 5 and max.12 calibrators.

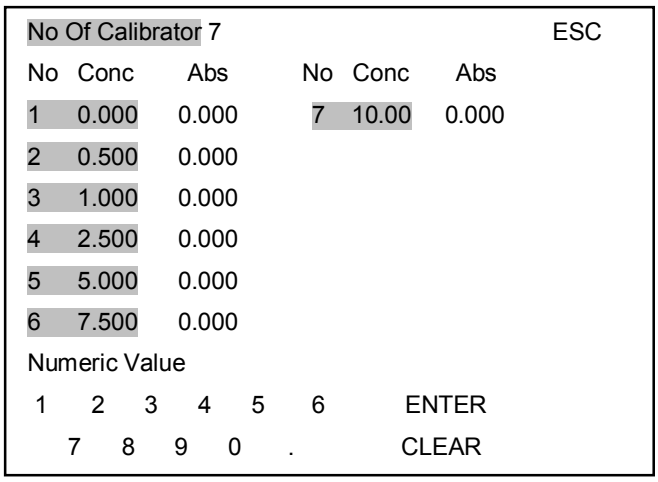


Concentration Entry:

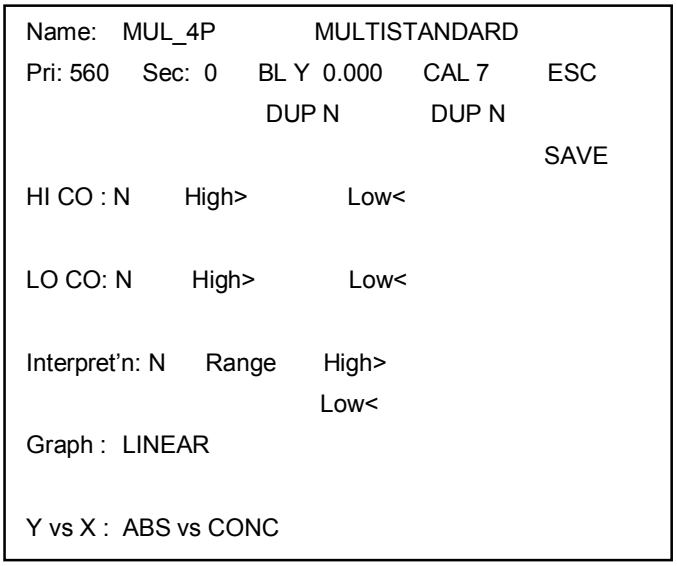
After entering the number of calibrators, concentration and absorbance column will come on the display as shown below.

To enter concentration values select 0.000 in Conc. column corresponding to the standard and enter the concentration value. e.g. for entering Concentration of standard 4 Select 0.000 in fourth row of Conc. Column and enter the concentration by selecting the numerals.

(Note: The concentration value should be either in ascending or descending order.)



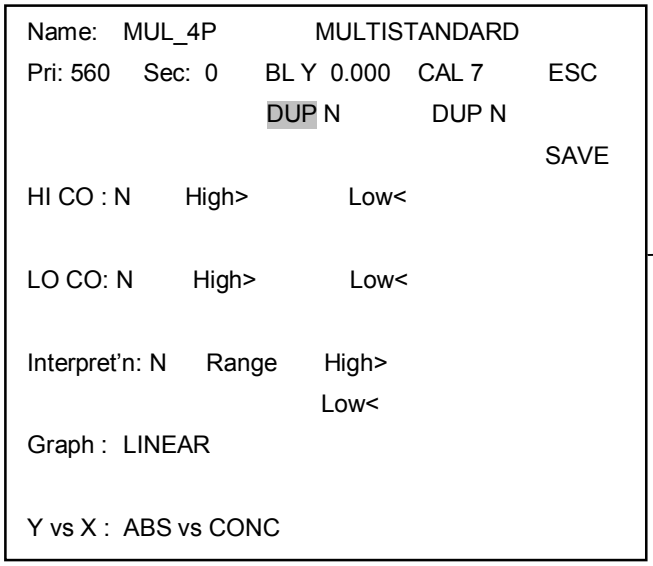
Screen after entry of calibration will be displayed as follows -

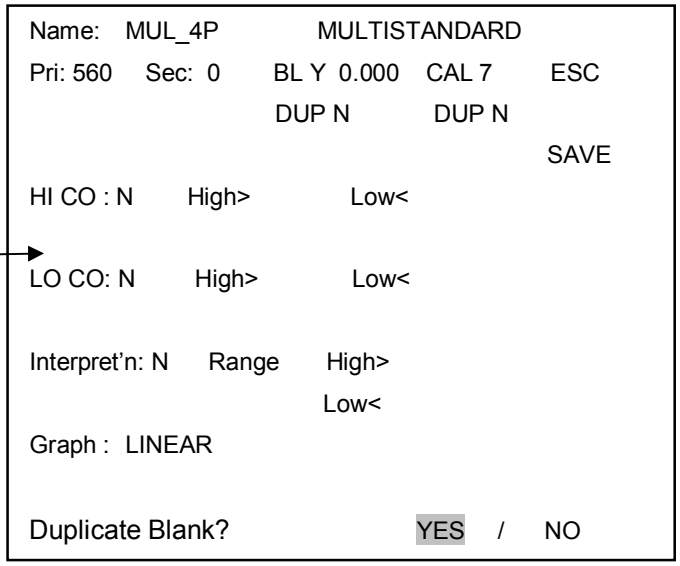


G. Selection of Duplicate Blank and calibrators

For Duplicate Blank:

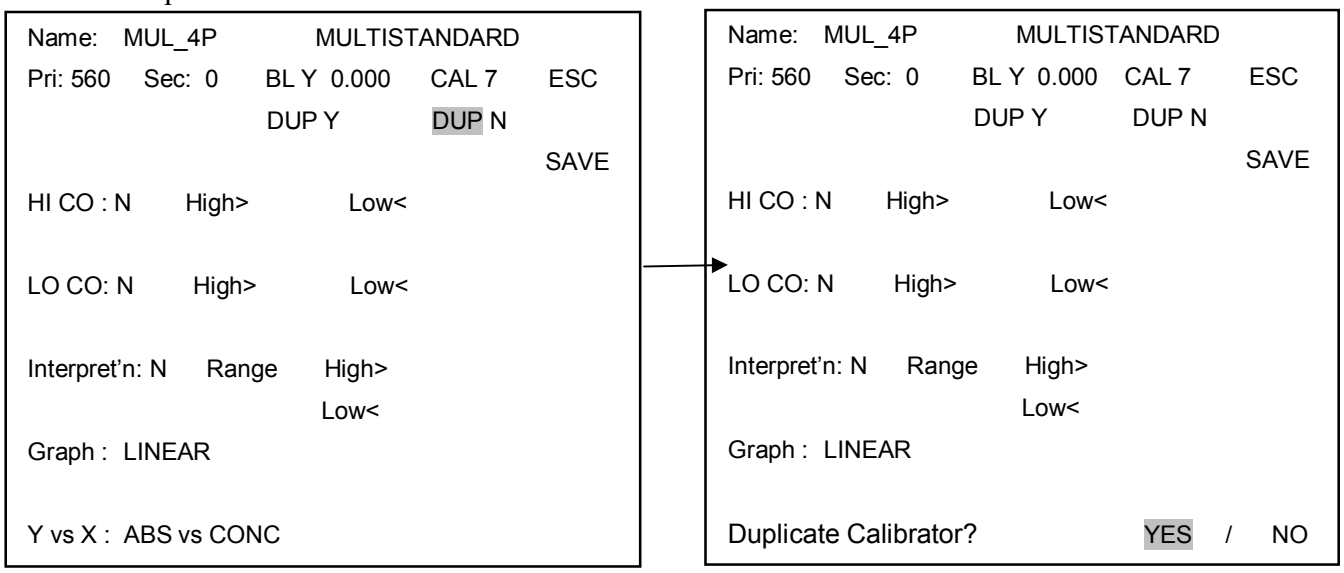
Select touch zone "DUP" below the "BL Y" After selecting "DUP" instrument will display message "Duplicate Blank? Yes/ No" as shown below. Select "Yes" for Duplication of Blank.



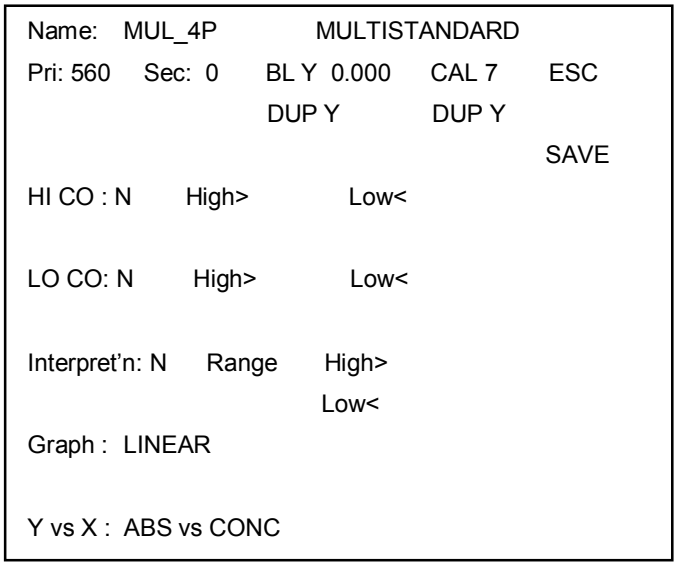


For Duplicate Calibrators:

To select Duplicate Calibrator select Touch Zone "DUP" below the "CAL 7". After selecting "DUP" instrument will display message "Duplicate Calibrator? Yes/No" as shown below. Select "Yes" for Duplication of calibrators.



Screen after standard entry & selection of duplicate – Blank & Calibrators.



H) Graph type along with its scales:

There are three types of graphs in Multistandard. They are mentioned as follows -

1. Linear (LINEAR)
2. Point to Point (PT TO PT)
3. 4 Parameters

There are five types of scales for X and Y axis

LOGABS vs CONC (X-axis = Concentration v/s Y-axis = LOG of ABS.)

ABS vs LOGCONC (X-axis = LOG of concentration v/s Y-axis = Absorbance)

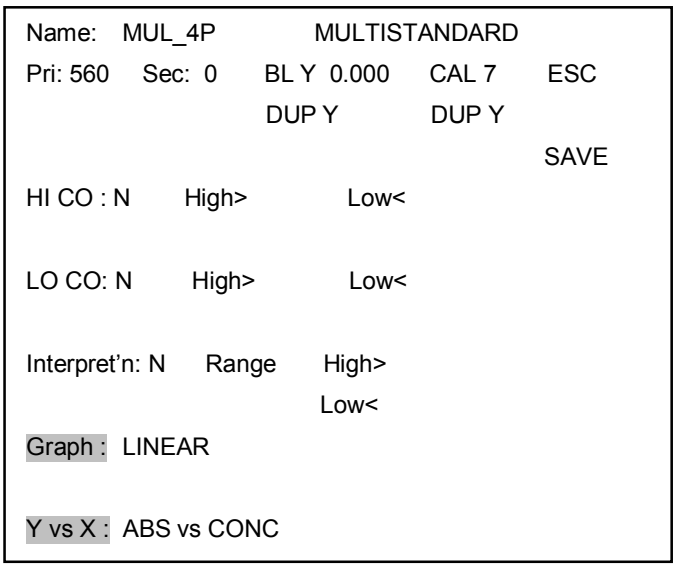
LOGITABS VS LOGCONC (X-axis = LOG of concentration v/s Y-axis = LOGIT of Absorbance)

ABS vs CONC (X-axis = Concentration v/s Y-axis = Absorbance)

LOGABS vs LOGCONC (X-axis = LOG of concentration v/s Y-axis = LOG of absorbance)

Selection of Graph

Select Graph type as per the details given in the reagent manual by selecting Touch Zone “Graph”.

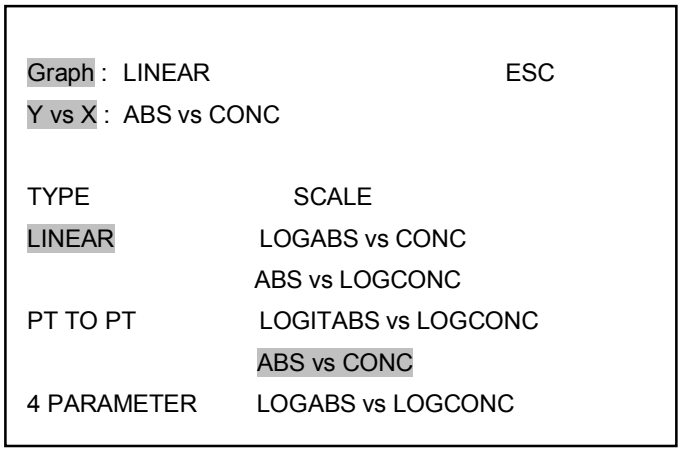


1. Linear mode graph type:

After Selecting the "Graph" follow screen will come on the display.

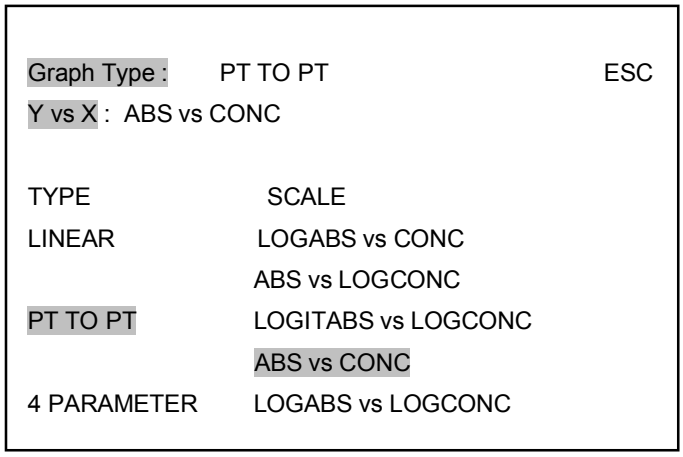
Select Graph type as Linear.

Select scale as per the details given in the reagent manual.



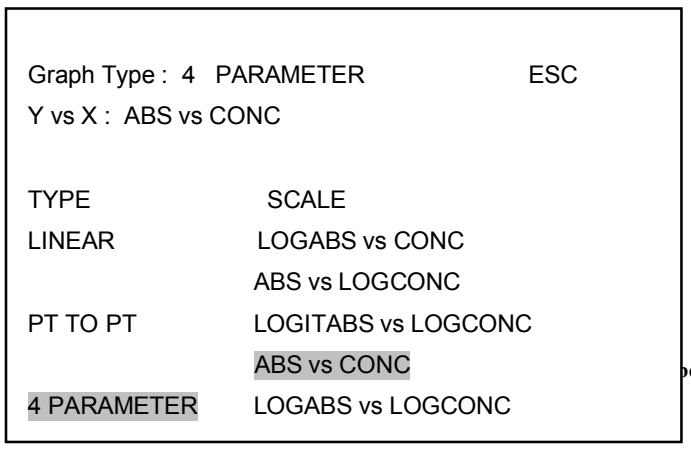
2. Point to Point Graph Type:

Select touch zone "PT to PT" abs scale of graph 'ABS vs. CONC'.

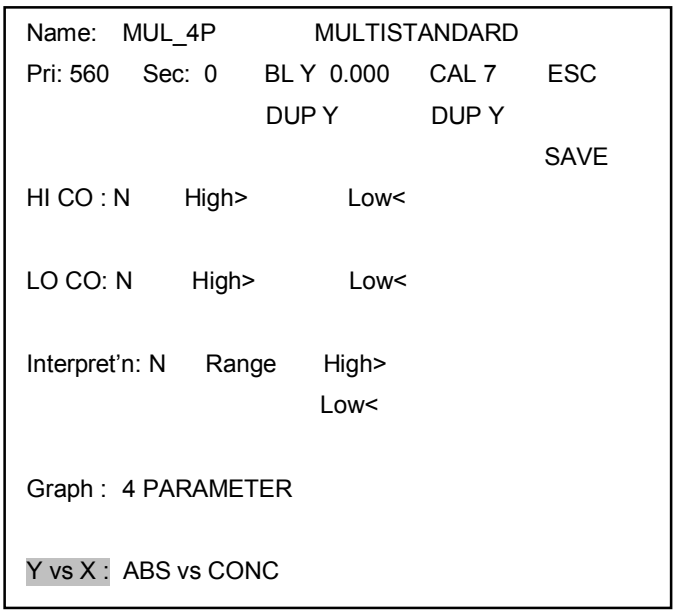


3. 4 Parameters Graph Type:

Select touch zone "4 Parameters" & abs scale of graph as 'ABS vs. CONC'. Remember that it's default scale type is "ABS vs CONC".

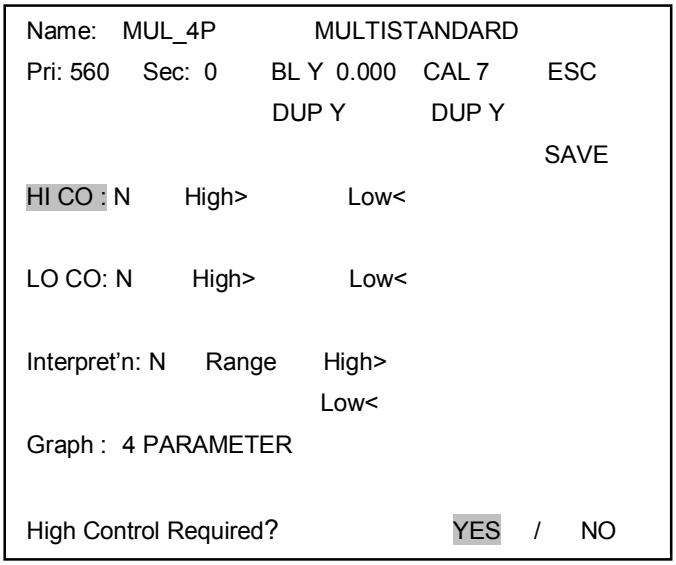


Select the scale type touching the required zone.

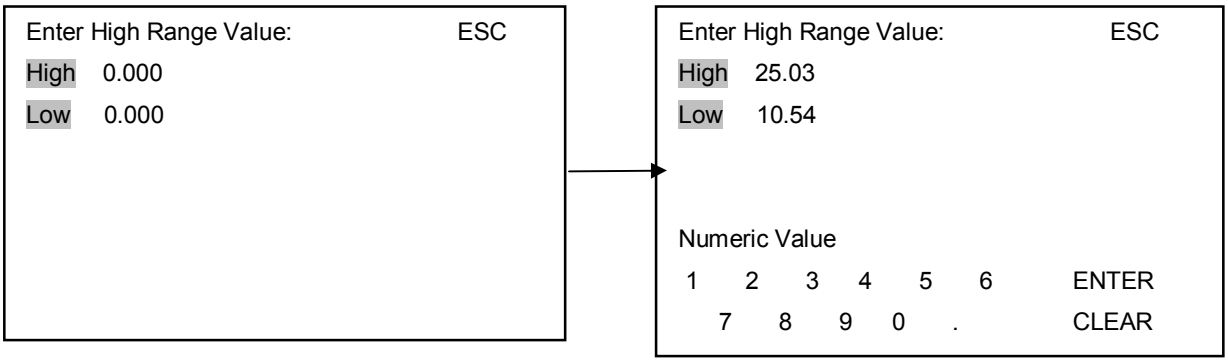


I. Selection of Controls

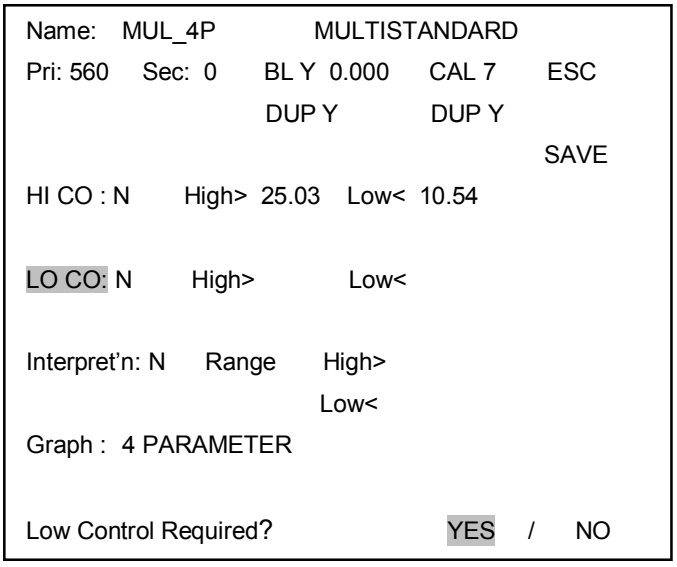
For High control select touch zone 'HI CO: N' Following message appears: "High Control Required? Yes / No". Select 'YES' and then enter range of control "HIGH" and "LOW".



Enter range of control “HIGH” and “LOW” as per reagent manual.



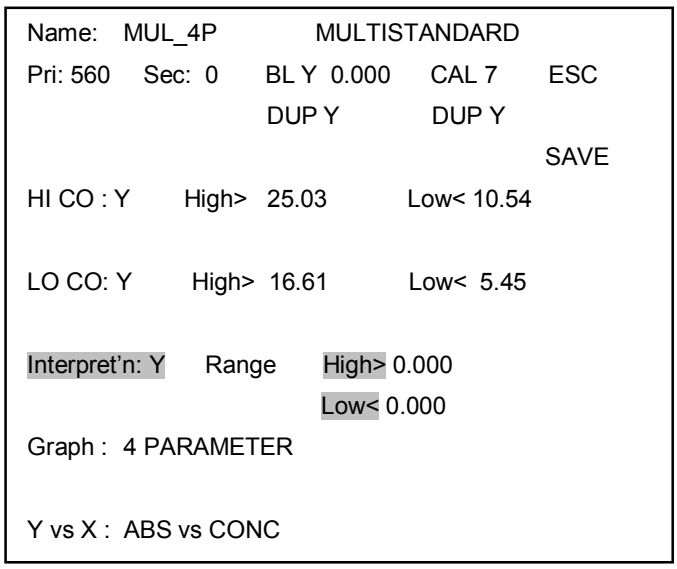
Similarly, for Low Control select touch zone ‘LO CO: N’ It will display the message “Low Control Required? Yes / No”. Select ‘YES’ and then enter range of control “HIGH” and “LOW”.



(Note: Entry of LO CO is similar to that of HI CO)

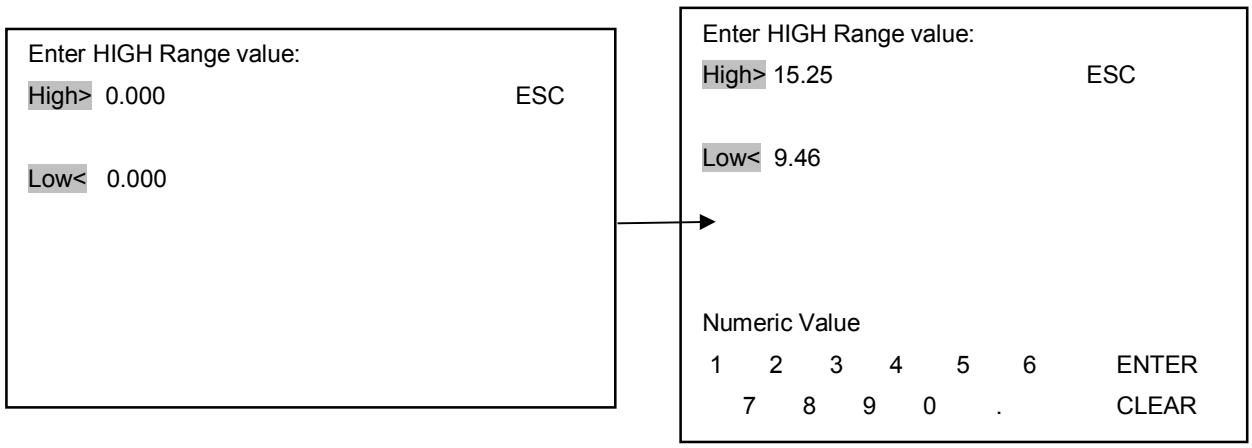
J. Normal Range selection for interpretation of samples:

For interpretation of specimen result (POSITIVE or NEGATIVE), enter normal range given in REAGENT MANUAL. Select "Interpretation: N". It will change to "Interpretation: Y". Then select "HIGH>" and "LOW<" to enter normal range.



All the results whose concentration is coming above the High Range will be considered as positive and coming below the Low Range will be consider as negative. The results having concentration in between High and Low range will get remarks **'Equivocal' = 'EQ'.**

Enter Normal Range for positive and negative samples.



After entering all the parameters save the test by selecting "SAVE" option.

```
Name:   MUL_4P          MULTISTANDARD
Pri: 560   Sec:  0     BL Y  0.000     CAL 7      ESC
                       DUP Y           DUP Y
                                                  SAVE
HI CO : Y      High>  25.03        Low< 10.54

LO CO: Y       High> 16.61         Low< 5.45

Interpret'n: Y  Range      High> 15.25
                           Low< 9.46
Graph :  4 PARAMETER

Y vs X :  ABS vs CONC
```

(*Same way you can make a test for Single standard, % Absorbance and uptake)

8.6. Percentage Absorbance

The Percentage Absorbance Mode requires one calibrator (read singly or duplicate). In this mode, calibrator is considered to have a concentration of 100%. The absorbance's of unknown samples are read and compared to the calibrator absorbance, and reported as % concentration of calibrator. Refer 8.5 for parameter entry.

```
Name:              % ABSORBANCE
Pri: 405   Sec: 0      BL Y  0.000     CAL  1     ESC
                       DUP N           DUP N
                                                  SAVE
HI CO : N      High>          Low<

LO CO: N       High>          Low<

Interpret'n: N   Range      High>
                           Low<
```

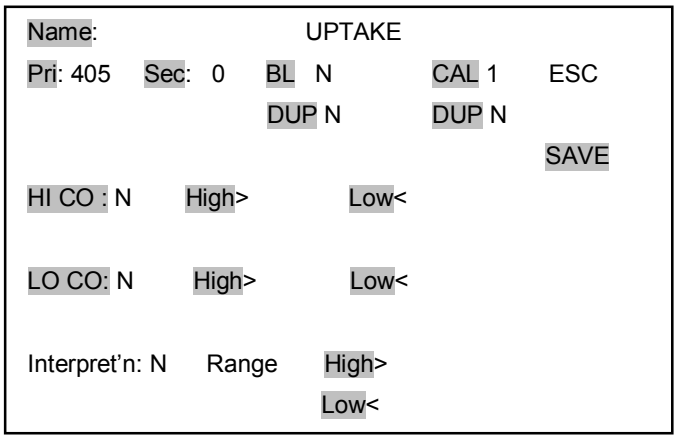
8.7. Uptake

In this mode the instrument accepts the calibrator singly or in duplicate and then calculates the concentration based on the single point standard curve passing through the point 0.000

A single calibrator/standard of a known concentration is used to calibrate the instrument so that the concentration of unknown samples can be calculated according to Beer's Law

Sample Concentration = Calibrator Absorbance * Calibrator Concentration

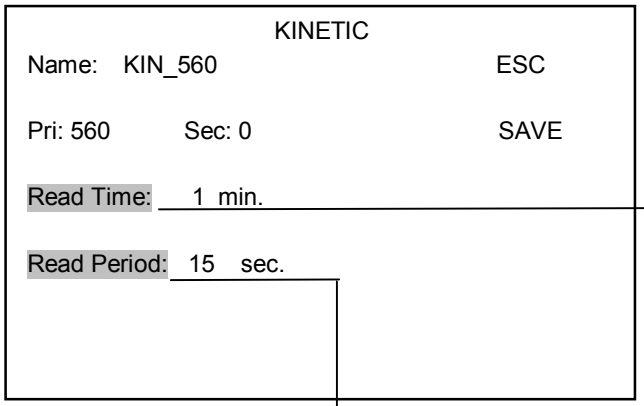
Sample Absorbance

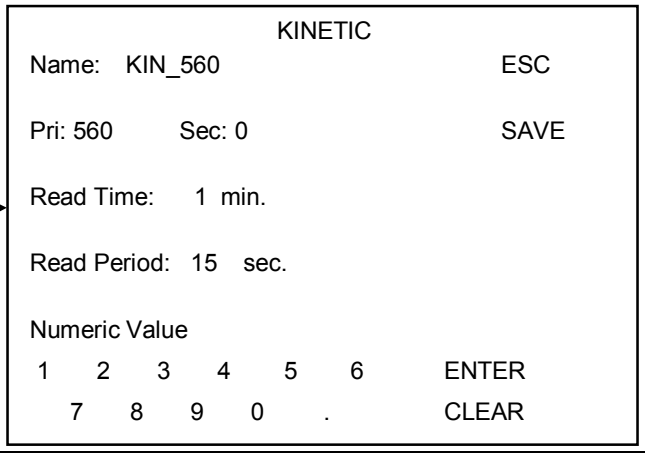


Please refer 8.5 for parameter entry.

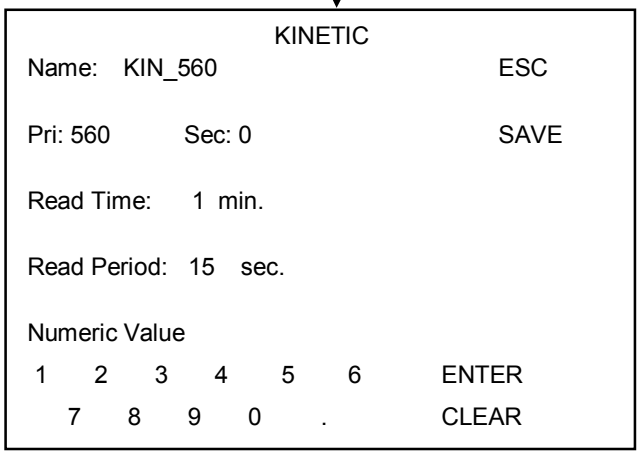
8.8. Kinetic

After entering Test Name and Filter values, select Read Time and Read Period



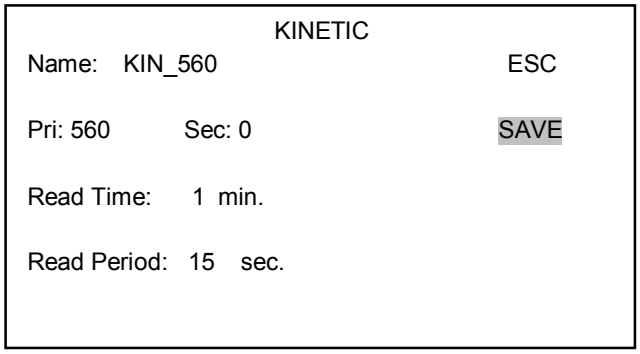


"Read Time" is total read period of the whole test. You need to enter it only in minutes.

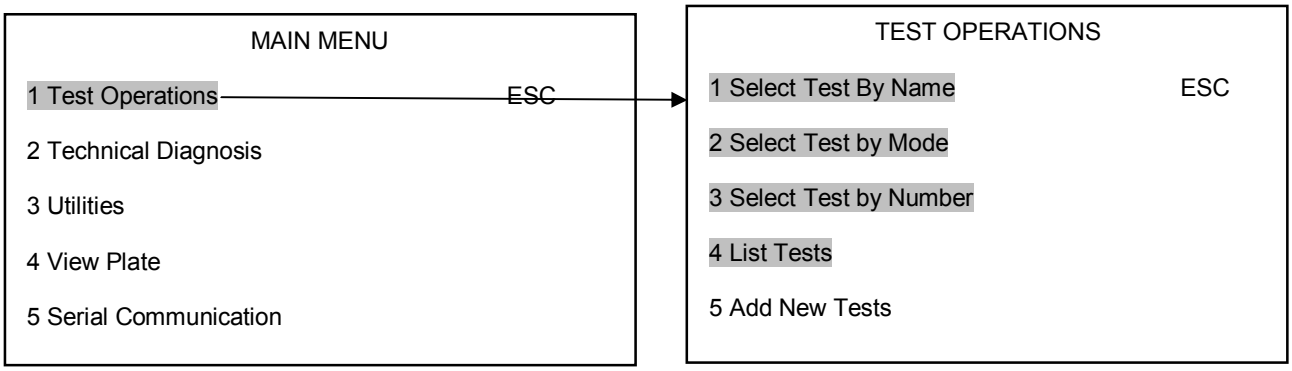


"Read Period" is time interval between two readings. User must enter it in seconds.

Finally select the "Save" option in order to save the test in KINETIC mode



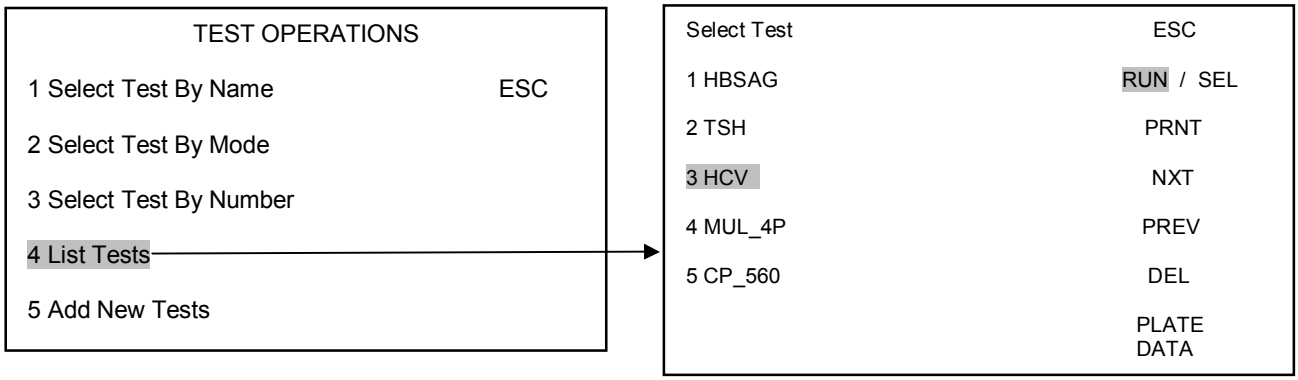
9. RECALLING AND RUNNING OF STORED TEST/PROGRAMS



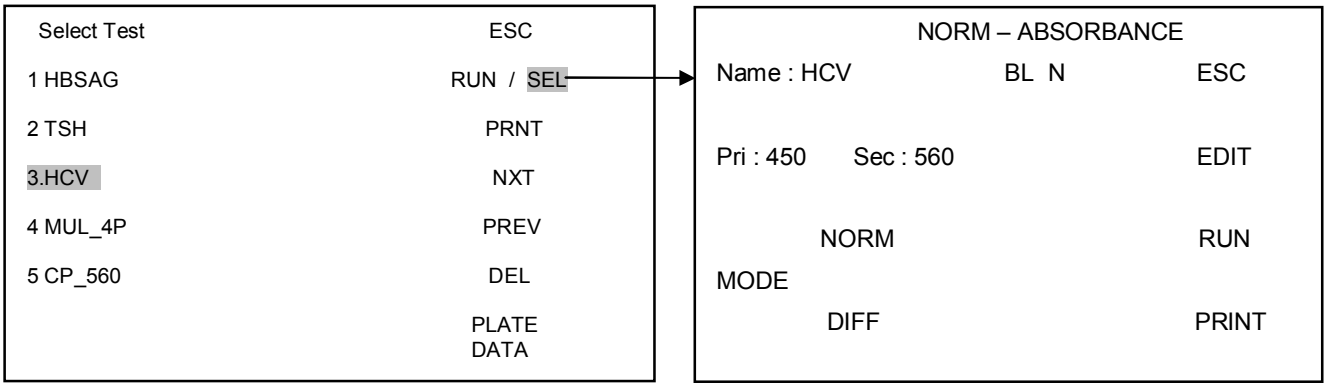
Test can be recalled by Name, Mode, Number or by List test.

The entire saved tests are available on the List Test or on the first screen after initialization.

User can directly RUN the test by selecting RUN option present on the screen.

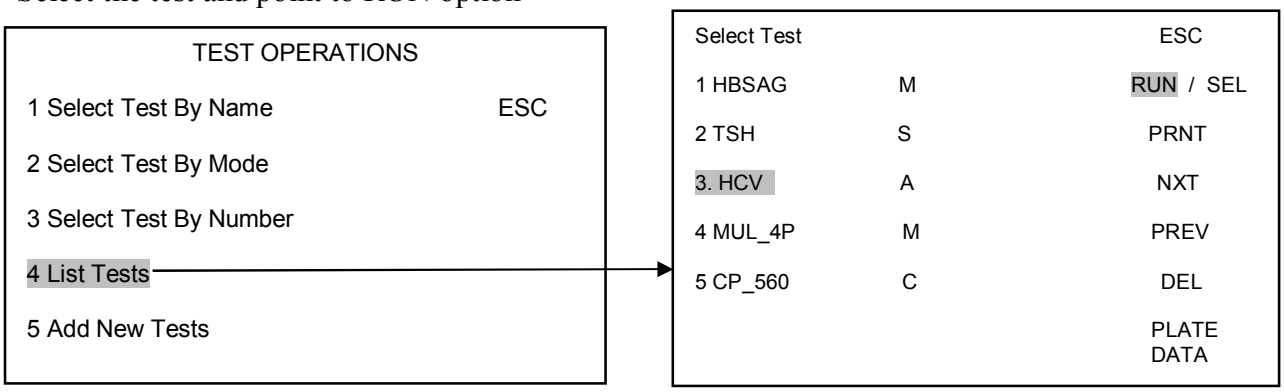


Tests can be selected with the help of SEL option present on the Select Test screen in order to EDIT / PRINT the test parameters entered before saving the test.



9.1. Absorbance Mode:

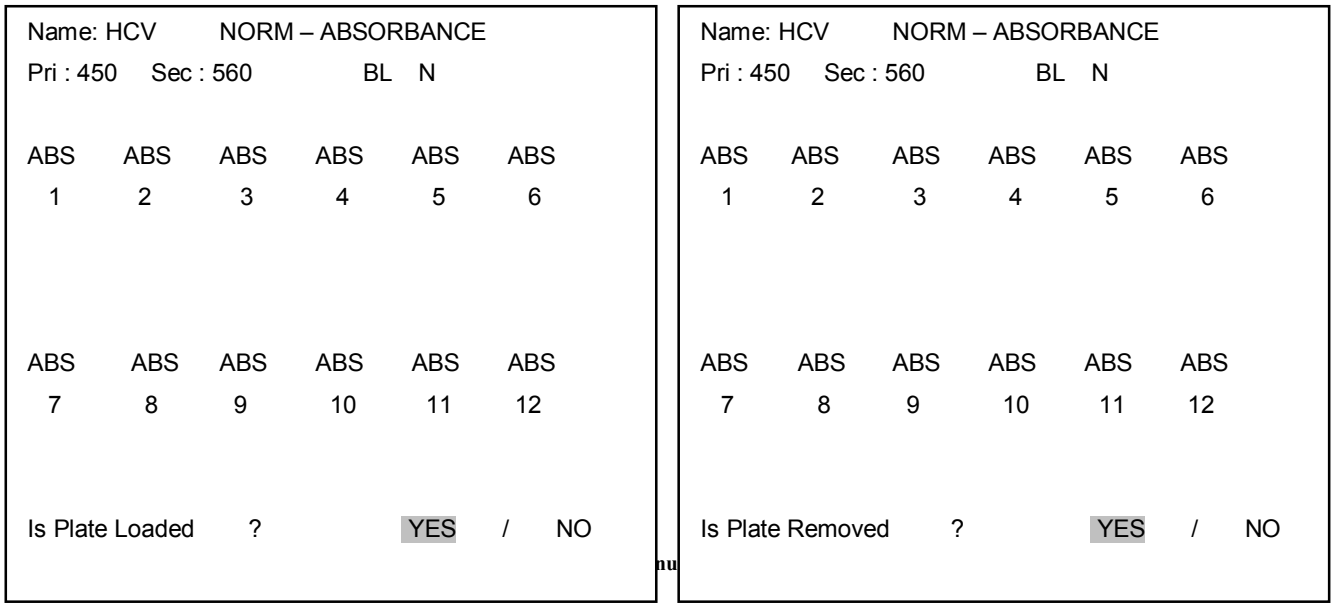
Select the test and point to RUN option



On selecting RUN option it will display following screen.

The instrument will ask "Is Plate Loaded? YES / NO", select 'Yes'. Instrument will read the absorbance using mechanical plate movement. After completion of reading it will ask:

"Is Plate Removed? YES / NO". Remove the plate and Select 'YES'**.**



Details of absorbance of all wells in table format for each strip will be displayed on the screen as shown below.

Name: HCV NORM – ABSORBANCE

Pri : 450 Sec : 560 BL N

ABS 1	ABS 2	ABS 3	ABS 4	ABS 5	ABS 6
0.028	0.145	0.100	0.017	0.089	0.135
--	--				
--					
--					
--					
0.071	0.123	0.113	0.054	0.116	0.060

ABS 7	ABS 8	ABS 9	ABS 10	ABS 11	ABS 12
0.362	0.078	0.410	1.440	0.746	0.224
--	--				
--					
--					
--					
0.112	0.111	0.093	2.568	0.396	0.015

ESCPRINTMATRIX SEND PLATE LOAD NEXT

In this operation if you keep BLANK YES

The first well of first strip will be considered as blank and instrument will give the absorbance of remaining all well with blank subtraction from original absorbance.

The "PRINT MATRIX" will print the details of entire plate with well identification and absorbance of that well, like…..

A

W1	W2	W3	W4	W5	W6
0.125	0.250	0.350	0.450	0.550	0.650..

Using "SEND PLATE" plate data can be sent to computer using either USB or SERIAL RS232.

"LOAD NEXT" is used to load the Next Plate in order to get the absorbance of next plate

Example Print-out of ABSORBANCE test obtained from ELISA Reader

After running the plate in Absorbance mode, user can take the print of the result in the form of Print matrix which will be printed as follows –

NORM-ABSORBANCE

Name : HCV

BL N

Pri : 450 Sec : 560
HCV, 21/07/08,

A											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.028	0.145	0.100	0.017	0.089	0.135	0.362	0.078	0.410	1.440	0.746	0.224
B											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.058	0.151	0.386	2.553	0.111	1.479	2.593	0.081	2.517	0.781	0.730	0.005
C											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.065	2.596	0.135	0.142	0.141	0.182	0.108	0.112	1.585	1.530	0.405	2.635
D											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.072	0.150	2.630	0.143	2.650	0.077	0.159	0.170	1.504	0.071	0.426	0.222
E											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
2.541	0.140	0.149	0.091	0.166	0.173	2.653	0.191	0.097	2.659	0.252	0.222
F											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
2.614	2.682	0.185	0.130	2.648	0.167	0.176	0.071	2.686	0.853	0.907	0.426
G											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.056	0.163	2.571	0.155	0.147	0.119	2.618	0.081	0.085	0.070	0.407	2.591
H											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.071	0.123	0.113	0.054	0.116	0.060	0.112	0.111	0.093	2.568	0.396	0.015.

Differential Absorbance Mode: In differential absorbance mode the instrument will give the absorbance difference each set of "ODD" number strip and EVEN number strip.

Name: ABS DIFF– ABSORBANCE

Pri : 560 Sec : 0

ABS 1	ABS 2	ABS 3	ABS 4	ABS 5	ABS 6
	0.900		1.700		0.900
	0.200		1.000		1.800
	0.300		1.100		1.900
	0.400		1.200		2.000
	0.500		1.300		2.100
	0.600		1.400		2.200
	0.700		1.500		2.300
	0.800		1.600		2.400
ABS 7	ABS 8	ABS 9	ABS 10	ABS 11	ABS 12
	0.100		0.900		1.700
	0.200		1.000		1.800
	0.300		1.100		1.900
	0.400		1.200		2.000
	0.500		1.300		2.100
	0.600		1.400		2.200
	0.700		1.500		2.300
	0.800		1.600		2.400

ESC PRINTMATRIX SEND PLATE LOAD NEXT

It is showing the absorbance only for even number strips. This absorbance values are actually differences between each well of strip 1 and well of strip 2.You can get the difference between set of 1-2, 3-4, 5-6, 7-8, 9-10 and 11-12. It is not possible to change this combination.

In "PRINT MATRIX", you will get the print of entire plate data with actual absorbance of each well and difference of absorbance between ODD well and EVEN well, like

A

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.300	0.279	0.524	0.497	0.816	0.499	0.082	0.474	0.651	0.331	0.394	0.562
0.000	0.021	0.000	0.028	0.000	0.316	0.000	-0.391	0.000	0.320	0.000	-0.168

B

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
0.506	0.584	0.648	0.194	0.472	0.457	0.822	0.346	0.679	0.387	1.047	0.130
0.000	-0.077	0.000	0.453	0.000	0.015	0.000	0.476	0.000	0.292	0.000	0.918

9.2. Cut off Mode

After recalling the test saved in Cut-Off mode, it will display following screen.
User can take the print of the test parameters by selecting "PRNT" option present on the screen. It will print all the details of the test parameters alongwith QC equations.

Name: HCV POS- Cut Off
Pri: 560 Sec: 0 ESC

	No	Factor	QC	QCVal	Mes.	EDIT
BL	1		Y	0.100	0.000	RUN
NC	2	1.000	Y	0.150	0.000	PRNT
PC	2	1.000	Y	0.500	0.000	
LC	0	1.000	N			
CC	0	1.000	N			

CUTFAC: 0.100
CUTABS: 0.1*PC+CF

QC1	N	Interpretation :
QC2	N	Greyzone % (Y) 10.00
QC3	N	Cut off Index (N)
QC4	N	Range

To change values press EDIT

A) For running the test in CUTOFF mode select the particular test and point to RUN option present on the "List Test" screen.

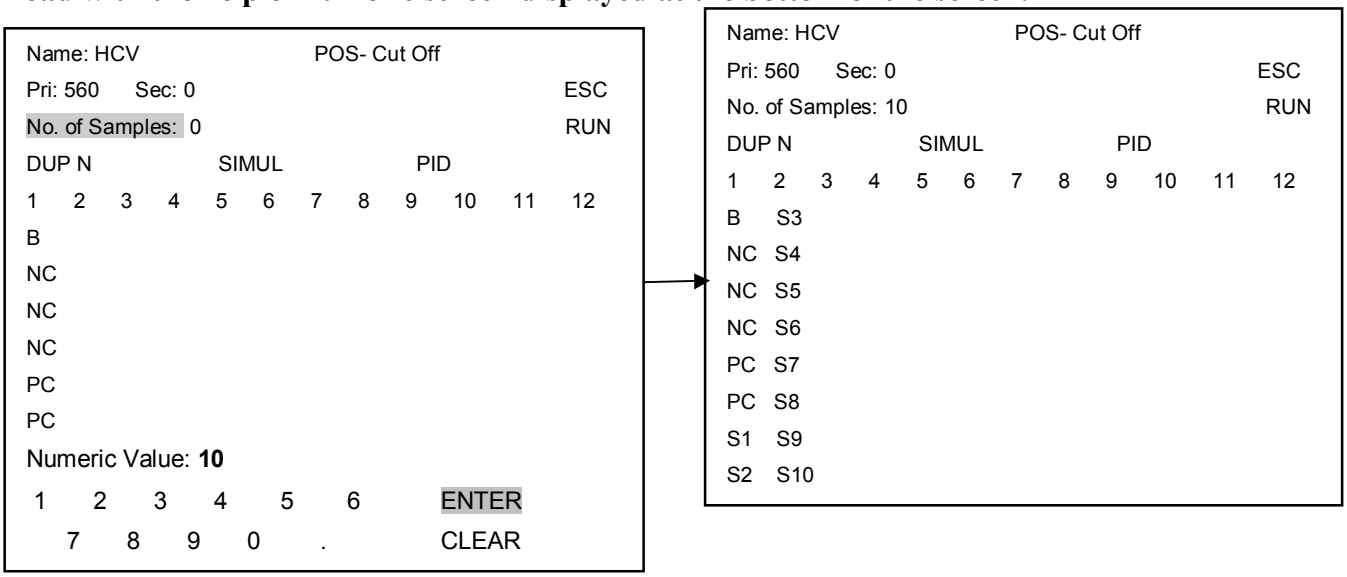
Select Test ESC

1 HBSAG	M	RUN / SEL
2 TSH	S	PRNT
3 HCV	C	NXT
4 MUL_4P	M	PREV
5 CP_405	C	DEL
		PLATE DATA

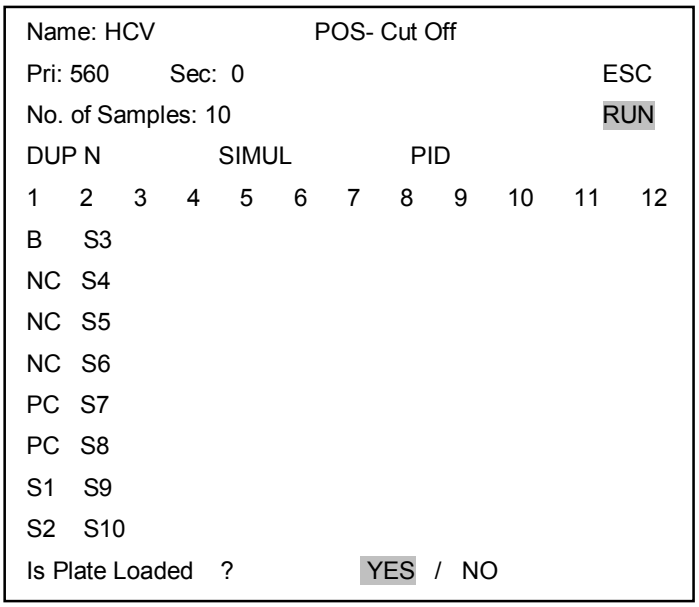
Name: HCV POS- Cut Off
Pri: 560 Sec: 0 ESC
No. of Samples: 0 RUN
DUP N SIMUL PID

	1	2	3	4	5	6	7	8	9	10	11	12
B												
NC												
NC												
NC												
PC												
PC												

B) It shows the 12 strips horizontal with 8 wells vertical with blanks and controls loaded in first strip. Select the 'No. of Samples' and enter the total Number of samples you want to load with the help of numeric screen displayed at the bottom of the screen.



C) After entering No. of samples, select RUN. The plate-loading tray will come out and the following message will appear: "Is plate loaded? YES / NO"



D) Here the plate is loaded in the direction that controls should go in first. Select "YES".

The instrument will read the controls and samples.

Following message appears: "Is plate removed? YES / NO". Remove the plate and select YES.

```
Name: HCV                POS- Cut Off
Pri: 560    Sec: 0                                   ESC
No. of Samples: 10                                   RUN
DUP N          SIMUL          PID
1   2   3   4   5   6   7   8   9   10   11   12
B   S3
NC  S4
NC  S5
NC  S6
PC  S7
PC  S8
S1  S9
S2  S10
     Is Plate Removed?          YES   /   NO
```

E) After selecting YES, result screen will appear with the measured values of average blank, average of all controls and the cut off absorbance. To check the results of samples, select option 'Display value'

```
Name: HCV              POS- Cut Off
Pri: 560  Sec: 0                                    ESC
     No  Factor  QC    QCVal   Mes.    Rem    ACCEPT
BL   1         Y     0.100   0.050           TEST
NC   2   1.000 Y     0.150   0.098
PC   2   0.100 Y     0.500   2.658           PRINT
LC   0   1.000 N
CC   0   1.000 N
CUTFAC: 0.200        CUTABS: 0.563           Display
                                             VALUE
QC1  2.560     QC2
QC3            QC4                           LOAD
                                             NEXT
Range % 10.00
```

F) 'DISPLAY VALUE' option will display the result of all samples along with the controls selected.

Name: HCV	POS- Cut Off	ESC
Pri: 560 Sec: 0	BL Y	
Range PERCENTAGE % 10.00		NXT
	Pos: 0.330	
CUT ABS= 0.300	Neg: 0.270	PREV

NO	SAMP	ABS	AVG	INDEX	REM	PID
A1	B	0.050	0.050			
B1	NC					
--						
--						
G1	S1	0.200	0.200	0.254	NEG	PQR-1
H1	S2	1.854	1.854	7.245	POS	PQR-2

PRINT RESULTS	SAVE RESULTS	PRINT MATRIX	PLATE OPT.

G) By selecting 'ACCEPT TEST' option you can save this test with the details of controls absorbance. Next time it is possible to run the same test without loading controls. This means that the previous stored values of controls can be used.

All the details are in table format, as per row and column shown on the screen. You can obtain the print of the same format by selecting option 'PRINT RESULTS'. To check the results of next samples, choose option 'NXT', and then print it in format as shown on the screen by option 'Print Results'

You can obtain the print in matrix format, by selecting option 'PRINT MATRIX'.

In matrix form you will get the print as per your tray/plate for all the wells. Instrument prints seven different parameters in print matrix for a single well.

ROW IDENTIFICATION	A, B, C,D,……
WELL NUMBER	W1, W2, W3, W4…..
WELL ID OR SAMPLE NUMBER	BL, NC, PC, OR S1, S2, S3, …..
PATIENT IDENTIFICATION	RAMESH, VIKAS, etc.
WELL ABSORBANCE	0.050, 0.098, 0.085, …
SAMPLE CONCENTRATION	0.738, 0.689, 2.578,…
INTERPRETATION / REMARKS	POS or NEG or EQ

Example Print-out of POS-CUTOFF test obtained from ELISA Reader

POS-CutOff

Name : HCV
Pri : 560 Sec : 0

	NO	Factor	QC	QCVal	Meas.
BL	1		Y	0.100	
NC	2	0.000	Y	0.150	0.000
PC	2	0.100	Y	0.500	0.000
LC	0	1.000	N		
CC	0	1.000	N		

CUTFAC : 0.100
CUTABS : .1*PC+CF

QC1	N	Interpretation :	
QC2	N	Greyzone%(Y)	10.0
QC3	N	Cutoff Range	Index (N)
QC4	N		

HCV, 21/07/08

A

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
B	S4	S12	S20	S28	S36	S44	S52	S60	S68	S76	S84
	OPD13	OPD21	OPD29	OPD37	OPD45	OPD53	OPD61	OPD69	OPD77	OPD85	OPD93
0.002	0.147	0.091	0.011	0.083	0.127	0.362	0.072	0.400	1.454	0.743	0.222
0.000	1.302	0.803	0.099	0.737	1.122	3.201	0.636	3.533	12.84	6.564	1.959
	POS	NEG	NEG	NEG	POS	POS	NEG	POS	POS	POS	POS

B

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
NC	S5	S13	S21	S29	S37	S45	S53	S61	S69	S77	S85
	OPD14	OPD22	OPD30	OPD38	OPD46	OPD54	OPD62	OPD70	OPD78	OPD86	OPD94
0.062	0.145	0.382	2.535	0.116	1.470	2.573	0.115	2.515	0.747	0.748	0.003
0.000	1.278	3.372	22.39	1.024	12.99	22.73	1.011	22.22	6.597	6.608	0.025
	POS	POS	POS	EQ	POS	POS	EQ	POS	POS	POS	NEG

C

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
NC	S6	S14	S22	S30	S38	S46	S54	S62	S70	S78	S86
	OPD15	OPD23	OPD31	OPD39	OPD47	OPD55	OPD63	OPD71	OPD79	OPD87	OPD95
0.040	2.573	0.129	0.159	0.133	0.217	0.077	0.091	1.584	1.557	0.502	2.638
0.000	22.72	1.136	1.405	1.177	1.917	0.677	0.804	13.99	13.75	4.434	23.30
	POS	POS	POS	POS	POS	NEG	NEG	POS	POS	POS	POS

D

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
PC	S7	S15	S23	S31	S39	S47	S55	S63	S71	S79	S87
	OPD16	OPD24	OPD32	OPD40	OPD48	OPD56	OPD64	OPD72	OPD80	OPD88	OPD96
0.080	0.157	2.630	0.141	2.642	0.058	0.155	0.159	1.515	0.071	0.423	0.209
0.000	1.389	23.23	1.246	23.33	0.516	1.370	1.403	13.38	0.628	3.732	1.850
	POS	POS	POS	POS	NEG	POS	POS	POS	NEG	POS	POS

E

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
PC	S8	S16	S24	S32	S40	S48	S56	S64	S72	S80	S88
	OPD17	OPD25	OPD33	OPD41	OPD49	OPD57	OPD65	OPD73	OPD81	OPD89	OPD97
2.562	0.172	0.198	0.061	0.182	0.165	2.656	0.156	0.080	2.616	0.259	0.224
0.000	1.517	1.751	0.536	1.612	1.457	23.46	1.377	0.705	23.11	2.291	1.978
	POS	POS	NEG	POS	POS	POS	POS	NEG	POS	POS	POS

F

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
S1	S9	S17	S25	S33	S41	S49	S57	S65	S73	S81	S89
OPD10	OPD18	OPD26	OPD34	OPD42	OPD50	OPD58	OPD66	OPD74	OPD82	OPD90	OPD98
2.626	2.612	0.055	0.116	2.649	0.188	0.176	0.052	2.638	0.855	0.899	0.419
23.19	23.07	0.483	1.023	23.40	1.660	1.553	0.460	23.30	7.548	7.942	3.699
POS	POS	NEG	EQ	POS	POS	POS	NEG	POS	POS	POS	POS

G

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
S2	S10	S18	S26	S34	S42	S50	S58	S66	S74	S82	S90
OPD11	OPD19	OPD27	OPD35	OPD43	OPD51	OPD59	OPD67	OPD75	OPD83	OPD91	OPD99
0.049	0.140	2.595	0.138	0.142	0.117	2.611	0.076	0.081	0.050	0.403	2.579
0.429	1.234	22.92	1.215	1.252	1.035	23.06	0.672	0.717	0.441	3.564	22.78
NEG	POS	POS	POS	POS	EQ	POS	NEG	NEG	NEG	POS	POS

H

W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
S3	S11	S19	S27	S35	S43	S51	S59	S67	S75	S83	S91
OPD12	OPD20	OPD28	OPD36	OPD44	OPD52	OPD60	OPD68	OPD76	OPD84	OPD92	OPD100
0.061	0.109	0.002	0.071	0.076	0.131	0.109	0.101	0.082	2.560	0.399	0.015
0.538	0.964	0.018	0.631	0.670	1.157	0.960	1.896	0.721	22.61	3.527	0.132
NEG	EQ	NEG	NEG	NEG	POS	EQ	NEG	NEG	POS	POS	NEG

9.2. A. Invalid Assay in Cut Off Mode

If any individual control behaves incorrectly and it's absorbance is not satisfying the QC check value of that control, the following message appears: "Invalid Assay" and a remark "HI" or "LO" for that particular control. OR if the QC1, QC2, QC3 and QC4, which has an other QC condition of controls (like some reagent manual gives condition PC-NC > 0.2 or NC/PC > 0.5) the following message appears: "Invalid Assay" and a remark either 'HI' or 'LO' for that QC condition.

Name: HBSAG POS- Cut Off
Pri: 560 Sec: 0 ESC

No	Factor	QC	QCVal	Meas.	Rem	ACCEPT
BL 1		Y	0.100	0.105	HI	TEST
NC 3	1.000	Y	0.150	0.200	HI	
PC 2	0.100	Y	0.500	0.456	LO	PRINT
LC 0	1.000	N				
CC 0	1.000	N				

CUTFAC: 0.200 CUTABS: 0.563 DISPLAY VALUE

QC1 2.560 HI QC2
QC3 QC4 LOAD
Invalid Assay NEXT

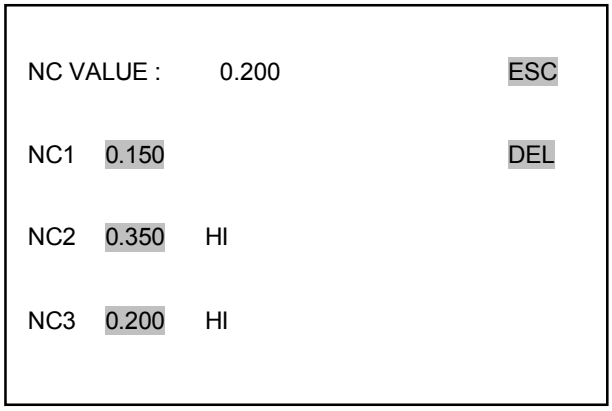
(NOTE: The absorbance of controls should not go above 3.50. If it is > than 3.50, it will show the remark 'HI' for that control. In such a case edit the control absorbance.)

In such case, delete an individual control, so that the average of remaining controls will satisfy the QC condition of that control as per reagent manual.

To select any control for deleting, you must select the touch zone as shown in the above screen.

When you select any particular control for deleting (suppose you have selected Negative Control (NC), 'HI' or 'LO' remark appear on the screen.

"Select EDIT / DEL key to proceed". To delete the control select 'DEL'. After deleting that control, the absorbance of that control will become zero and the average of controls will also get changed. Select 'ESC' option to come back to the Result screen.



When you go back, you will get the edited values for average of control with no remark for any control and no "Invalid Assay" message.

***NOTE**:

Make the blank absorbance valid in case the absorbance doesn't meet the QC conditions.

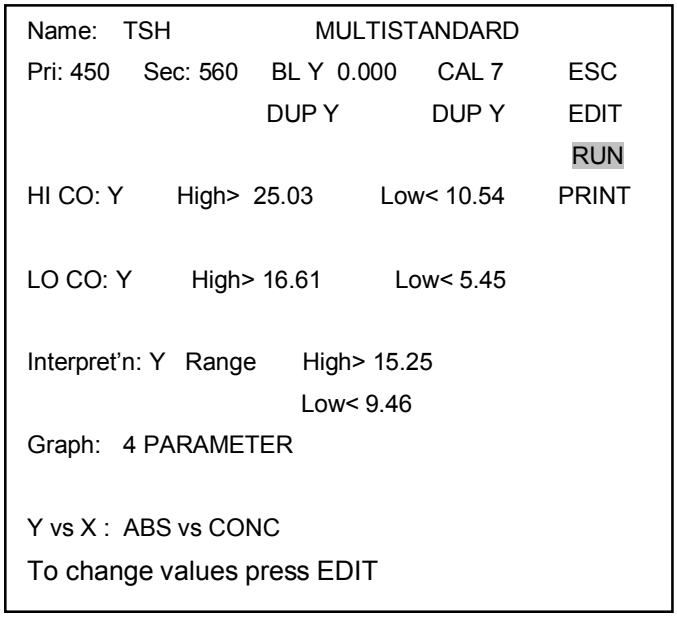
If necessary valid the control absorbance because the absorbance of the blank affect the absorbance of all controls and samples.

It is recommended that, for a test with single blank and single control, if absorbance doesn't satisfy QC conditions or if all controls of any single type (means all NC controls or all PC controls) doesn't meet the QC, the test will become totally invalid. It is not possible to make the VALID TEST and new controls have to be loaded.

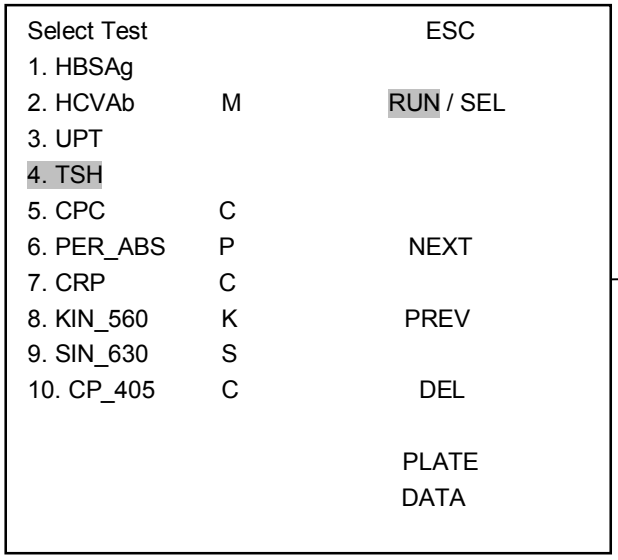
9.3. Multistandard

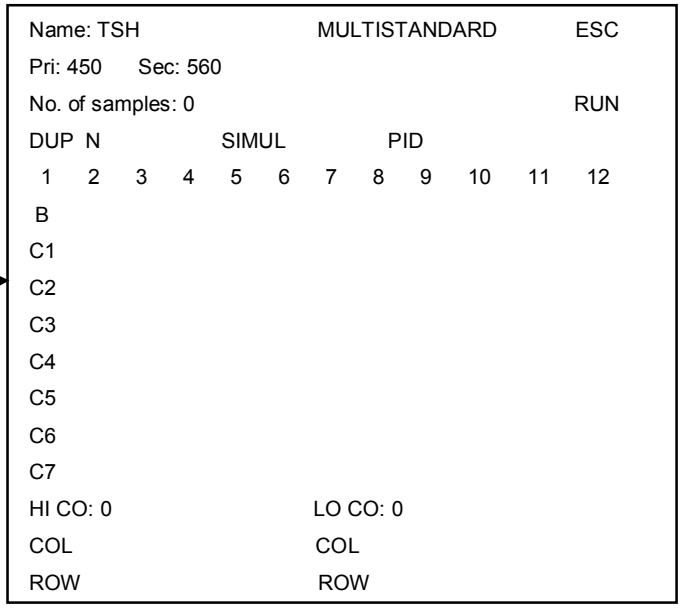
After recalling the test in multistandard mode it will display following screen. Take the print of the test parameters if required and select "Run" option. Or else you can directly run the test from the List Test screen.

Multi Standard Mode



A) For running the test in MUL_STD mode select the particular test and point to RUN option present on the screen. On selecting RUN option it will display following screen.

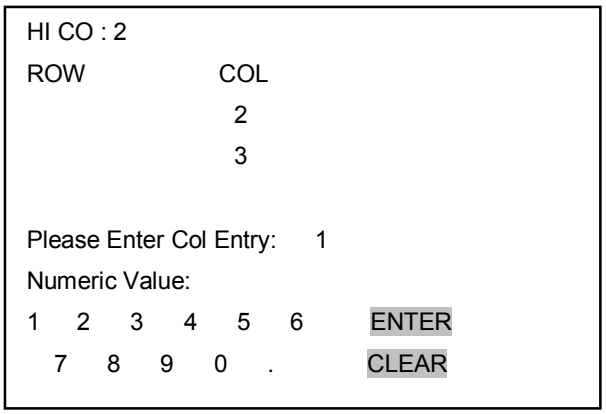




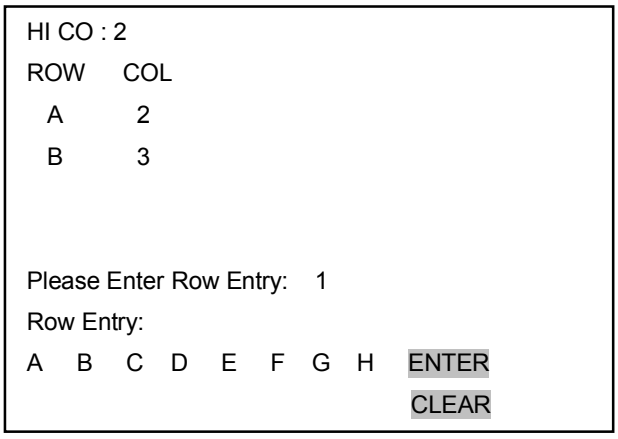
B) To enter total No. of HI controls, select "HI CO:" option and enter numeric value.

C) If you select No. of HI controls = 2, then you have to locate the position of HI controls by selecting column number and row number.

For column number entry select "COL" option and enter column number.



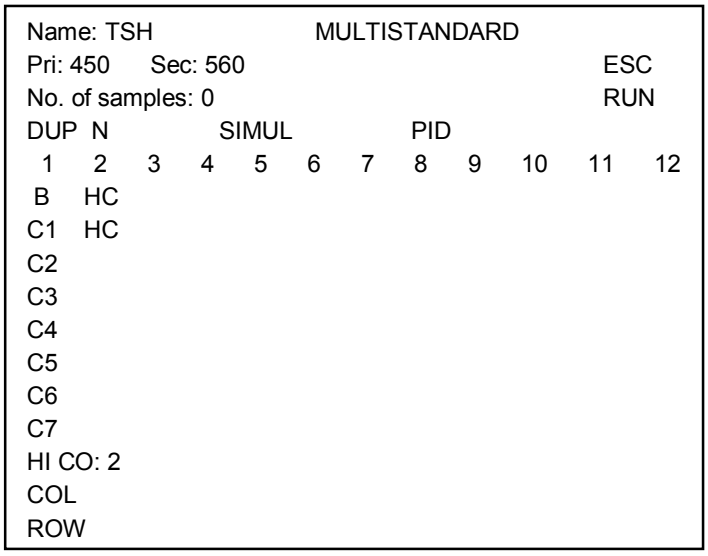
For row entry select "ROW" option and enter row position.



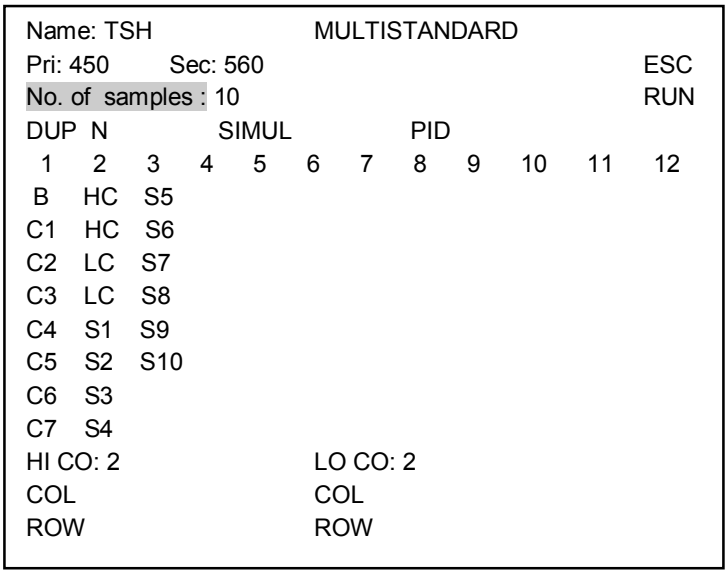
Similarly, you can enter No. of LO Controls and locate its positions.

D) You can locate Controls from first well or after last calibrator to last well of strip 12 in any test.

Suppose you select column 2 & row A for first HI control and column 2, row B for second HI control then the location of HI control will be display on screen as shown below.



E) Select No. of samples you want to run. In case of 10 samples, it will load 10 samples as follows -



F) Now Select RUN option so that readings can be taken in MULTI STANDARD mode.

The plate holder will come out and will display the message string- "Is Plate loaded YES / NO". The plate has to be loaded in such a way that the direction of the calibrators should go in first and then select 'YES'.

The instrument will read the absorbance of calibrators and samples. And finally display the string- "Is plate removed? YES / NO". Remove the plate and select 'YES'. The plate holder will go inside and following screen will be flashed on the display.

(Note: It takes maximum 6 min only in case of 4 parameter)

```
Name:            MULTI STANDARD                ESC
Pri:    Sec:     BL          CAL               NXT
                 DUP         DUP               PREV
Range   High >   Low <
HI  CO :  High >          Low <                SAVE
LO CO : High >            Low <              RESULT
NO      SAMP     ABS      AVG      CONC     REM      PID




Please Wait.....
It may take maximum 6 minutes.
LOAD  PRINT   PLATE   VIEW   ACCEPT   PRINT
NXT   MATRIX  OPT.    GRAPH  TEST     RESULTS
```

After reading it will display all the details of calibrators, samples and controls on the screen as shown below-

```
Name: TSH              MULTI STANDARD            ESC
Pri: 450  Sec: 560     BL   Y        CAL 7
                       DUP  N        DUP  N
Range   High > 15.25    Low <  9.46               NXT
HI  CO :  High > 25.03  Low <  10.54
LO CO : High >  16.61   Low <   5.45              PREV
NO    SAMP   ABS   AVG   CONC   REM    PID
A1    B      0.050 0.050                          SAVE
B1    C1     0.070 0.070  0.000                  RESULT
C1    C2     0.257 0.257  2.500
--
--
--
G1    S1     0.200  0.200  2.100   NEG   TSH-1
H1    S2     1.854  1.854  9.845   POS   TSH-2
LOAD  PRINT    PLATE   VIEW    ACCEPT    PRINT
NXT   MATRIX   OPT.    GRAPH     TEST    RESULTS
```

All the details as per row and column are shown on the screen. The printout of the same format can be obtained by selecting 'PRINT RESULTS'. To check the results of next samples, select 'NXT' and print the format shown on screen by option 'Print Results'.

You can get the print in matrix format, by selecting 'PRINT MATRIX'.

In matrix form you will get the print as per your plate for all the wells. Instrument will print seven different parameters in print matrix for a single well as follows:

ROW IDENTIFICATION	A,B, C,D,……
WELL NUMBER	W1, W2, W3, W4…
WELL ID OR SAMPLE NUMBER	B, C1, C2, C3, OR S1, S2, S3,..
PATIENT IDENTIFICATION	LUCAS, DUPONT, etc.
WELL ABSORBANCE	0.050, 0.098, 0.085, …
SAMPLE CONCENTRATION	0.738, 0.689, 2.578…
INTERPRETATION / REMARKS	POS, NEG, EQ,

Remember that Negative sign result is interpreted as zero both in printout as well as on screen.

Example Print-out of MultiStandard test obtained from ELISA Reader

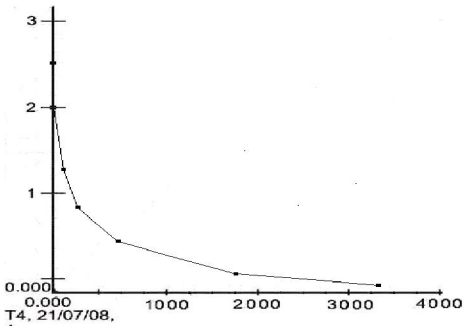
MULTI STDS

Name : T4
Pri : 450 Sec : 560

BL	N	DUP	N
CAL	7	DUP	N
Graph :		4 PARAMETER	
Y vs X :		ABS	vs CONC
HI	CO : N	High >	
		Low<	
LO	CO : N	High>	
		Low<	
Range	Y	High>	6.000
		Low<	4.000

No	Con	Abs
1	0.000	2.500
2	17.000	2.010
3	51.000	1.340
4	170.000	0.860
5	510.000	0.470
6	1700.000	0.230
7	3400.000	0.100

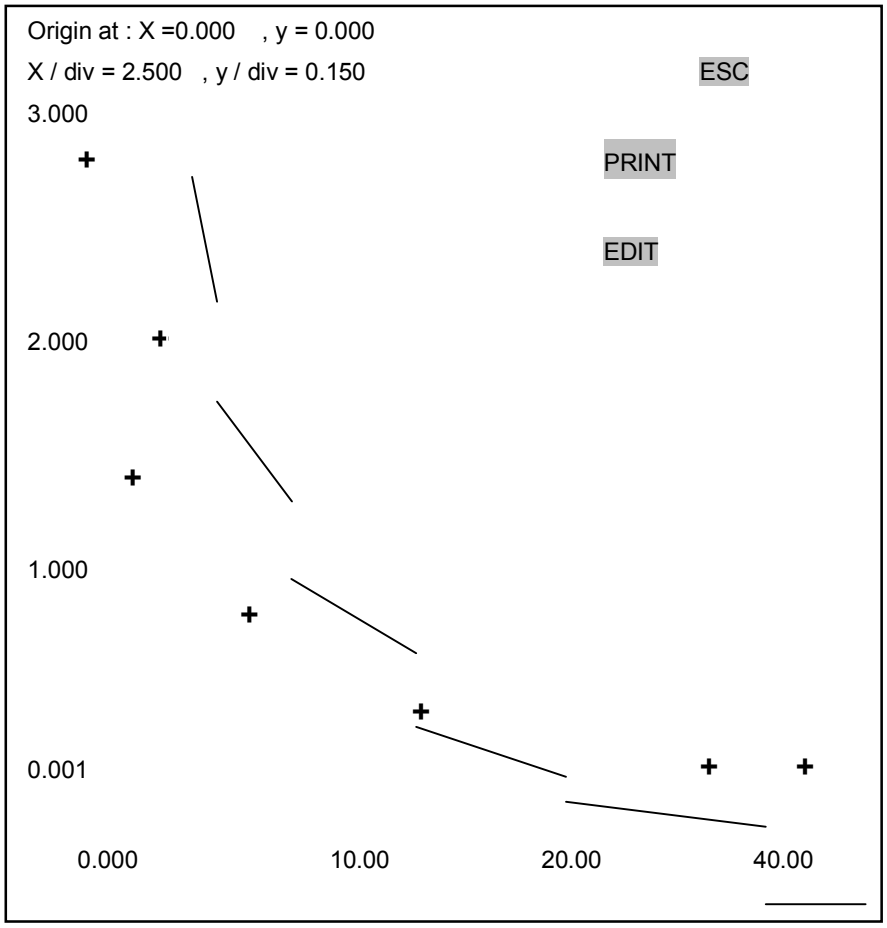
Origin at : x = 0.000, y = 0.000
x / div = 0.625, y / div = 0.126



T4, 21/07/08,

A											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C1	S2	S10	S18	S26	S34	S42	S50	S58	S66	S74	S82
	OP02	OP10	OP40	OP26							
2.500	2.566	0.711	0.728	0.796	0.423	0.744	0.728	0.768	0.141	0.700	0.151
0.000	10.00	3.175	3.226	3.275	1.880	2.203	2.240	2.255	0.527	2.141	0.475
		NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG	NEG
B											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C2	S3	S11	S19	S27	S35	S43	S51	S59	S67	S75	S83
	OP03	OP11	OP40	OP27							
2.010	2.485	1.432	1.448	1.412	0.755	0.709	0.756	0.729	0.173	0.700	0.134
17.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
C											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C3	S4	S12	S20	S28	S36	S44	S52	S60	S68	S76	S84
	OP40	OP12	OP20	OP28							
1.340	2.603	0.081	0.801	0.154	0.448	0.155	0.161	2.547	0.766	0.854	2.625
51.000	10.43	0.273	2.382	0.516	1.963	0.523	0.533	10.30	2.340	2.444	10.43
	POS	NEG	NEG	NEG	NEG	NEG	NEG	POS	NEG	NEG	POS
D											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C4	S5	S13	S21	S29	S37	S45	S53	S61	S69	S77	S85
	OP05	OP13	OP21	OP29							
0.860	2.609	0.092	0.804	0.153	0.800	0.156	0.157	2.615	0.803	0.803	2.589
170.00	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
E											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C5	S6	S14	S22	S30	S38	S46	S54	S62	S70	S78	S86
	OP06	OP14	OP22	OP30							
0.470	1.520	0.155	0.846	0.154	2.616	0.531	0.454	0.448	2.386	1.542	1.431
510.00	4.772	0.532	2.600	0.532	7.579	1.547	1.487	1.539	11.15	4.738	4.386
	EQ	NEG	NEG	NEG	POS	NEG	NEG	NEG	POS	EQ	EQ
F											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C6	S7	S15	S23	S31	S39	S47	S55	S63	S71	S79	S87
	OP07	OP15	OP23								
0.230	1.584	0.161	0.924	0.162	1.533	0.363	0.393	0.440	3.096	1.549	1.497
1700.00	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
G											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
C7	S8	S16	S24	S32	S40	S48	S56	S64	S72	S80	S88
	OP08	OP16	OP24								
0.100	1.490	1.419	1.410	0.149	1.456	0.159	2.447	2.637	1.415	1.454	1.453
3400.00	4.478	4.337	4.393	0.520	7.114	0.510	9.689	10.24	4.293	4.376	4.442
	EQ	EQ	EQ	NEG	POS	NEG	POS	POS	EQ	EQ	EQ
H											
W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
S1	S9	S17	S25	S33	S41	S49	S57	S65	S73	S81	S89
OP01	OP09	OP17	OP25								
1.539	1.498	1.478	1.524	0.161	2.520	0.146	2.489	2.503	1.453	1.468	1.511
0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

G) By selecting option 'View Graph:' key, the graph appears on the screen, with all the details of X-axis and Y-axis. Select 'PRINT' option to obtain the print out.

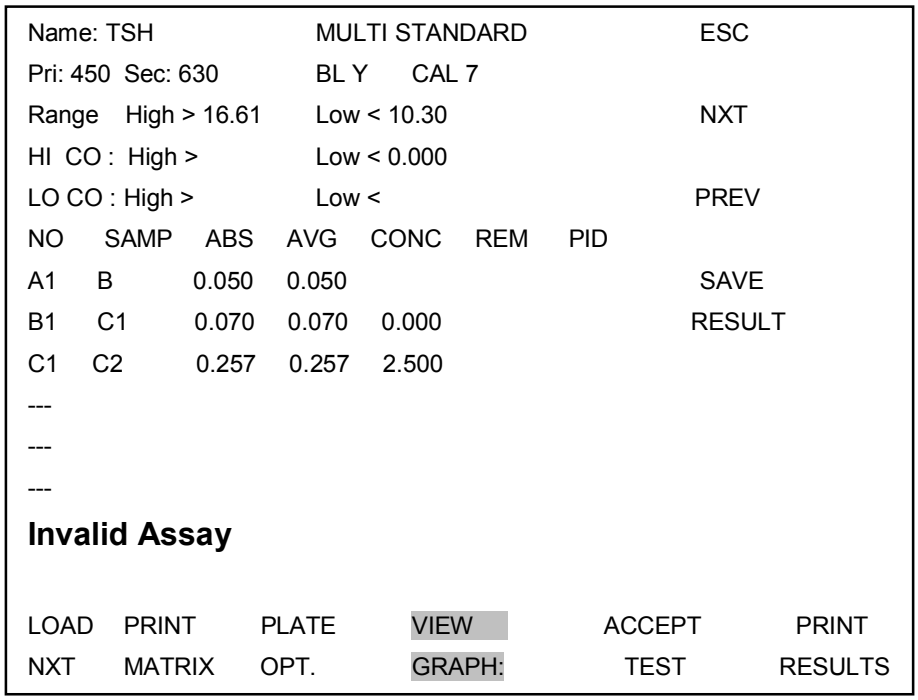


Select 'ACCEPT TEST' option to save this test with the details of calibrator absorbance. It is possible to run the same test without loading calibrators. The previous graph can be used for new samples.

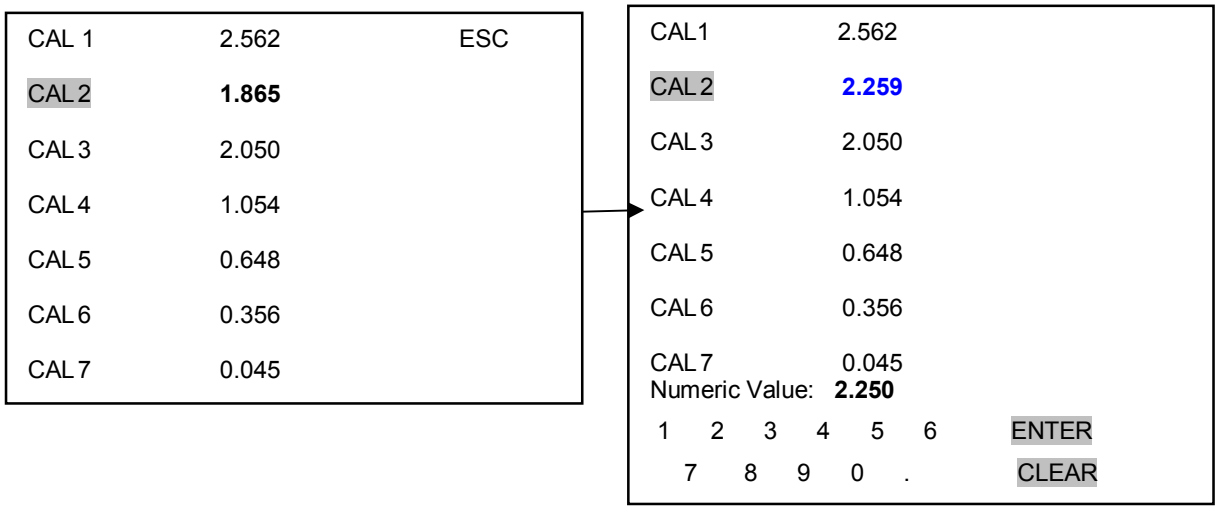
(* **NOTE:** If you do not want to run the calibrators each time, please select "ACCEPT TEST" option to save graph, whenever you run the test with calibrators.)

9.3.A. Invalid assay in Multi standard Mode

In Multi standard, the absorbance of calibrators should be in increasing or decreasing from one calibrator to the next calibrator. If any calibrator/s behave(s) incorrectly you will obtain a message "Invalid Assay" at bottom side of screen.



If Assay is Invalid then "Accept Test", "Save Results", "Print Matrix", "Save Plate" options are blocked. In such a case, select VIEW GRAPH option and change the ASSAY to VALID with the help of EDIT option present on the Graph screen.

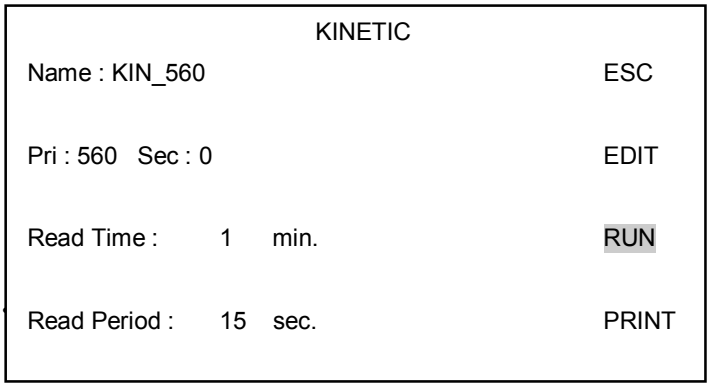


You can easily select any particular calibrator by touching that touch zone and edit the corresponding absorbance . After editing the calibrator's absorbance select "ESC". A message will appear: "PLEASE WAIT…" and the modified graph will appear on the screen.

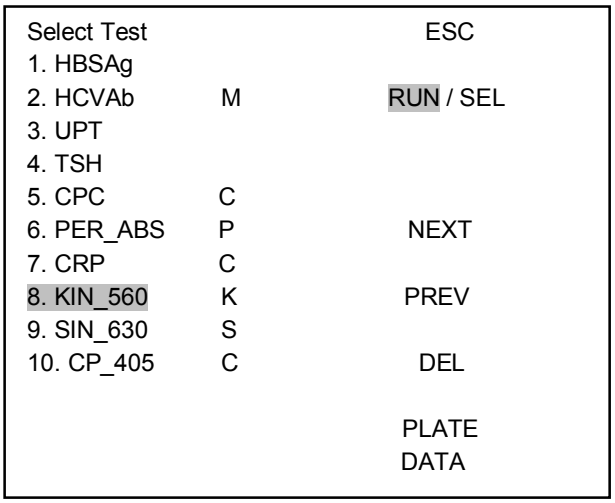
If calibrator's value being edited in Multistandard mode then "*Mod…" string is displayed in the print.

9.4. Kinetic:

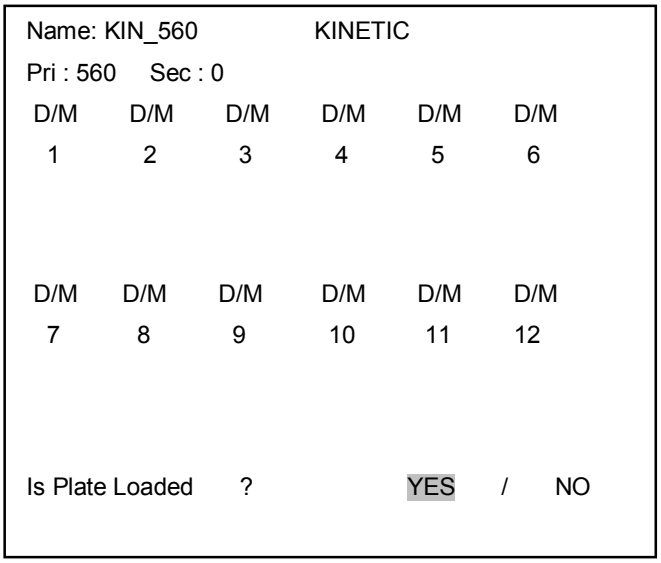
Select "RUN" to start to run the test in Kinetic mode.

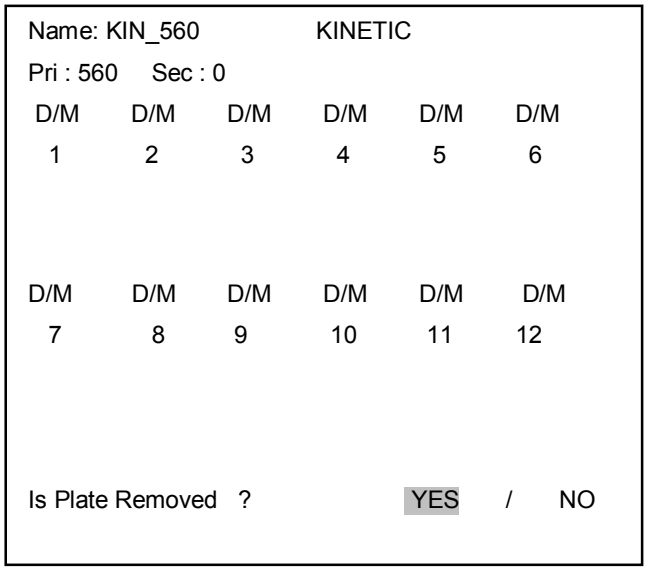


Or else you can directly run the test from the List Test screen by selecting RUN option present on the screen.

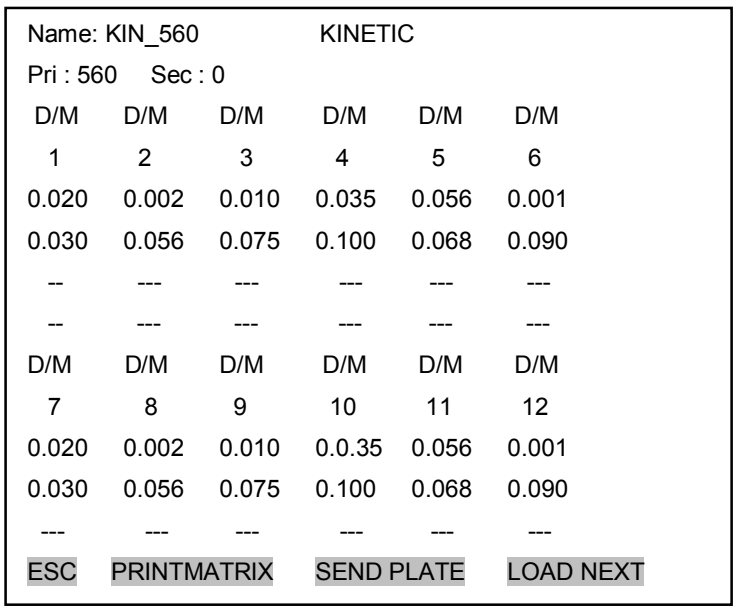


The “D/M” means delta per minute of reaction. When test will over, instrument will show you the “D/M” values of reaction done in each well.





It is showing the “D/M” values for each and every well in table format.



In “PRINT MATRIX”, you will get the print of entire plate data with initial absorbance of each sample, average delta values of each sample and “D/M” values of each well, like…

A

W1	W2	W3	W4	W5	W6	
0.200	0.100	1.200	0.300	2.600	0.900..	these are initial absorbance.
0.010	0.001	0.005	0.017	0.028	0.001..	these are average delta values.
0.020	0.002	0.010	0.035	0.056	0.001..	these are “D/M” values of each sample.

B

W1	W2	W3	W4	W5	W6
0.300	0.100	1.200	0.200	2.600	0.800..
0.015	0.028	0.037	0.050	0.034	0.045..
0.030	0.056	0.075	0.100	0.068	0.090..

On selecting “SEND PLATE” option user can send the plate data to computer with the help of USB or SERIAL communication.

“LOAD NEXT” is used to load the next plate.

- **Example Print-out obtained from ELISA READER**

KINETIC

Name : KIN_560

Pri : 560 Sec : 0

Read Time 1 min

Read Period 15 sec

KIN_D, 21/07/08,

	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10	W11	W12
A	0.160	2.653	0.843	0.831	0.889	0.515	0.835	0.822	0.838	0.228	0.786	0.232
	0.028	-0.004	-0.004	0.002	-0.002	-0.008	-0.008	0.020	0.017	-0.003	0.005	0.008
B	0.139	2.577	1.502	1.511	1.493	0.861	0.793	0.832	0.805	0.233	0.813	0.226
	0.061	0.004	-0.002	0.020	0.026	0.023	0.011	-0.012	0.030	-0.004	0.022	0.015
C	0.502	2.700	0.168	0.878	0.278	0.523	0.236	0.252	2.592	0.867	0.963	2.720
	0.042	0.001	0.004	0.011	0.014	0.014	0.029	0.037	0.005	0.030	0.009	0.018
D	0.536	2.730	0.196	0.897	0.260	0.897	0.257	0.255	2.720	0.907	0.912	2.698
	0.015	0.014	0.027	0.013	0.035	0.043	0.027	0.012	-0.000	0.030	0.004	-0.016
E	0.936	1.608	0.264	0.938	0.282	2.711	0.635	0.556	0.568	2.462	1.655	1.542
	0.036	0.024	0.021	0.027	-0.005	-0.008	-0.006	0.005	0.009	0.021	0.007	0.014
F	1.009	1.706	0.289	1.132	0.313	1.707	0.568	0.554	0.604	3.155	1.682	1.647
	0.078	0.055	0.057	0.055	0.044	0.077	0.067	0.040	0.040	0.012	0.036	0.054
G	1.559	1.565	1.448	1.485	0.225	1.523	0.239	2.547	2.715	1.490	1.542	1.532
	0.027	0.021	0.026	0.027	0.022	0.022	0.027	0.054	0.013	0.033	0.031	0.012
H	1.618	1.595	1.581	1.615	0.250	2.646	0.274	2.564	2.616	1.598	1.576	1.613
	0.050	0.031	0.047	0.018	0.037	0.017	0.079	0.007	-0.020	0.050	0.022	0.003

(Note: Same Procedure can be used to create and run the test in all other modes, like Single Standard, % Absorbance & Uptake)

10. RERUNNING ACCEPTED TESTS / PROGRAMS

"ACCEPT TEST" option is used to store the data of controls or calibrators. After running any test first time with controls or calibrators, you select option "Accept Test" to save the data of controls or calibrators, so that next time when you want to load the same test, there is no need to load controls or calibrators in ELISA plate. You can use previously stored data.

A) In "CUT OFF" Mode:

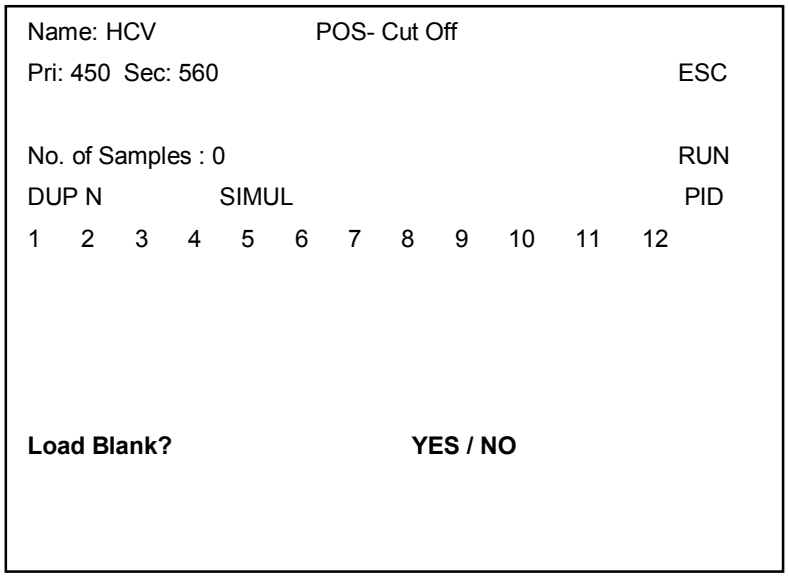
```
Name: HCV                POS- Cut Off
Pri: 450  Sec: 560                                   ESC
    No   Factor   QC    QCVal   Mes.    Rem        ACCEPT
BL  1            Y     0.100   0.050               TEST
NC  3   1.000    Y     0.150   0.098
PC  2   0.100    Y     0.500   2.658               PRINT
LC  0   1.000    N
CC  0   1.000    N
CUTFAC: 0.200            CUTABS: 0.563             Display
                                                   VALUE:
QC1  2.560       QC2
QC3              QC4                               LOAD
                                                   NEXT
```

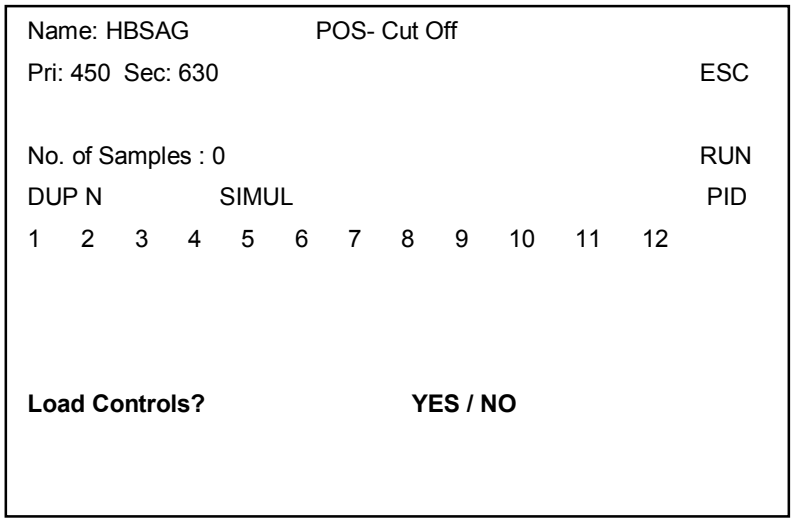
B) In "Multi standard" Mode:

```
Name: TSH                MULTI STANDARD                    ESC
Pri: 450  Sec: 560       BL Y     CAL 7
Range   High > 16.61     Low < 10.30                       NXT
HI  CO :  High >         Low < 0.000
LO CO : High >           Low <                             PREV
NO    SAMP   ABS    AVG    CONC    REM    PID
A1    B      0.050  0.050                                  SAVE
B1    C1     0.070  0.070  0.000                           RESULT
C1    C2     0.257  0.257  2.500
---
---
G1    S1     0.200  0.200  2.100   NEG    TSH-1
H1    S2     1.854  1.854  9.845   POS    TSH-2

LOAD   PRINT     PLATE     VIEW      ACCEPT     PRINT
NXT    MATRIX    OPT.      GRAPH     TEST       RESULTS
```

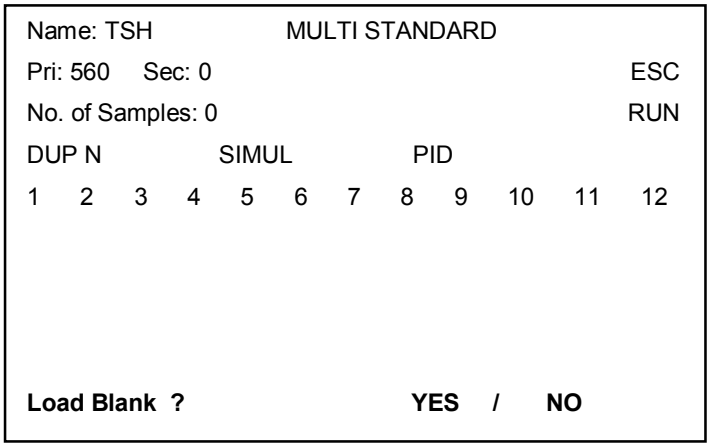
When you want to run such an accepted test, select 'RUN' option in test detail screen, in "CUT OFF" mode:

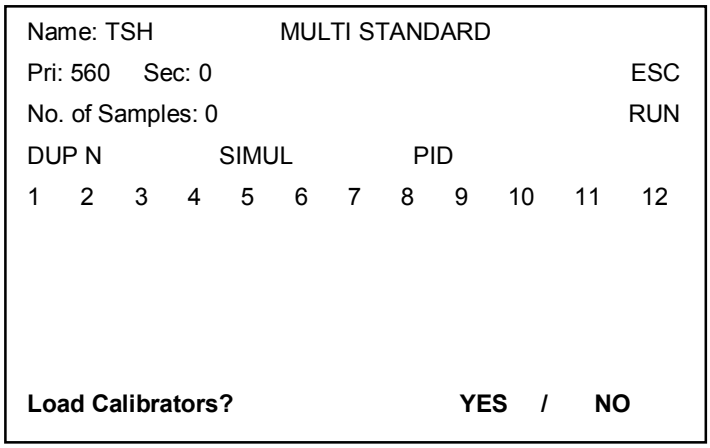




This time, the blank and controls will not be loaded directly and you will get the following questions: "Load Blank? YES / NO" and "Load Controls? YES / NO".
If you are running both, select 'YES', and if you want to use earlier stored data of controls select 'NO', so that you can run only samples to get their results without loading Blank and Controls.
If you want to load only 'Blank', select "Load Blank? YES" and
"Load Controls? NO".
In case if you are using previously Stored "Blank" and "Controls" then it will print following strings in the printout-
"Using Blank Stored value….." and "Using Controls Stored value…."

C) In Multi Standard / Single Standard / % Absorbance / Uptake Mode:





In Calibrator Mode, after asking "Load Blank? Yes / No" you will get the following question "Load Calibrators? Yes / No". If you are loading new calibrators and want the results of samples as per new graph select "Load Calibrators? YES".

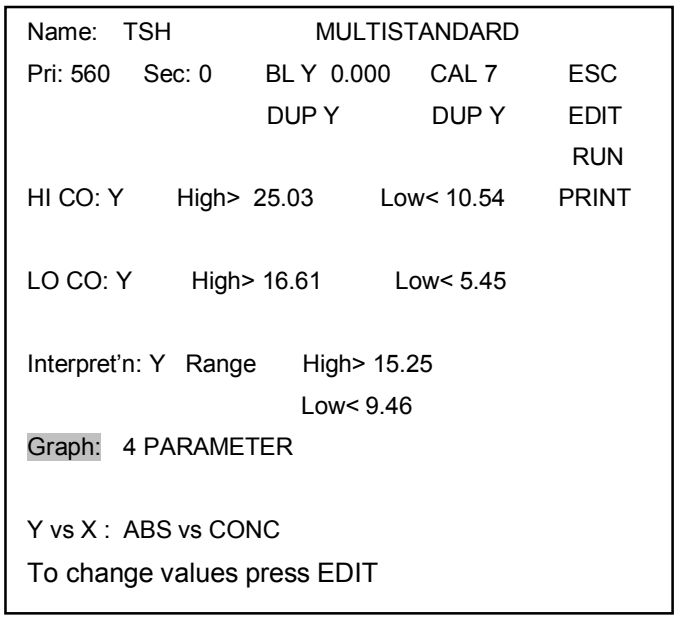
Or else, If you are not loading new calibrators and want to use previously stored graph select "Load Calibrators? No".

If you want to load only 'Blank', select "Load Blank? YES" and "Load Calibrators? NO".

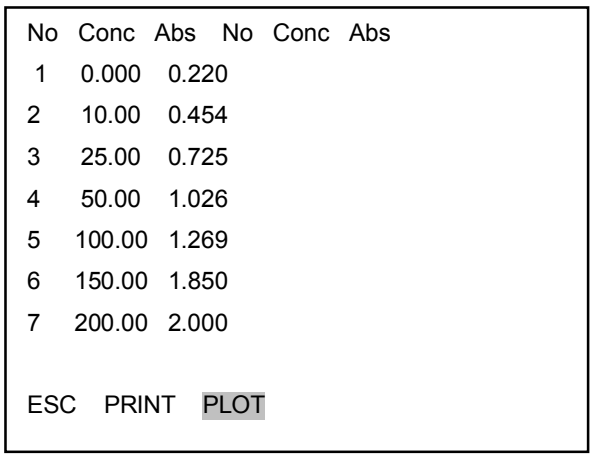
In case if you are using previously Stored "Blank" and "Calibrators" then it will print following strings in the printout-

"Using Blank Stored value….." and "Using Calibrator Stored value…."

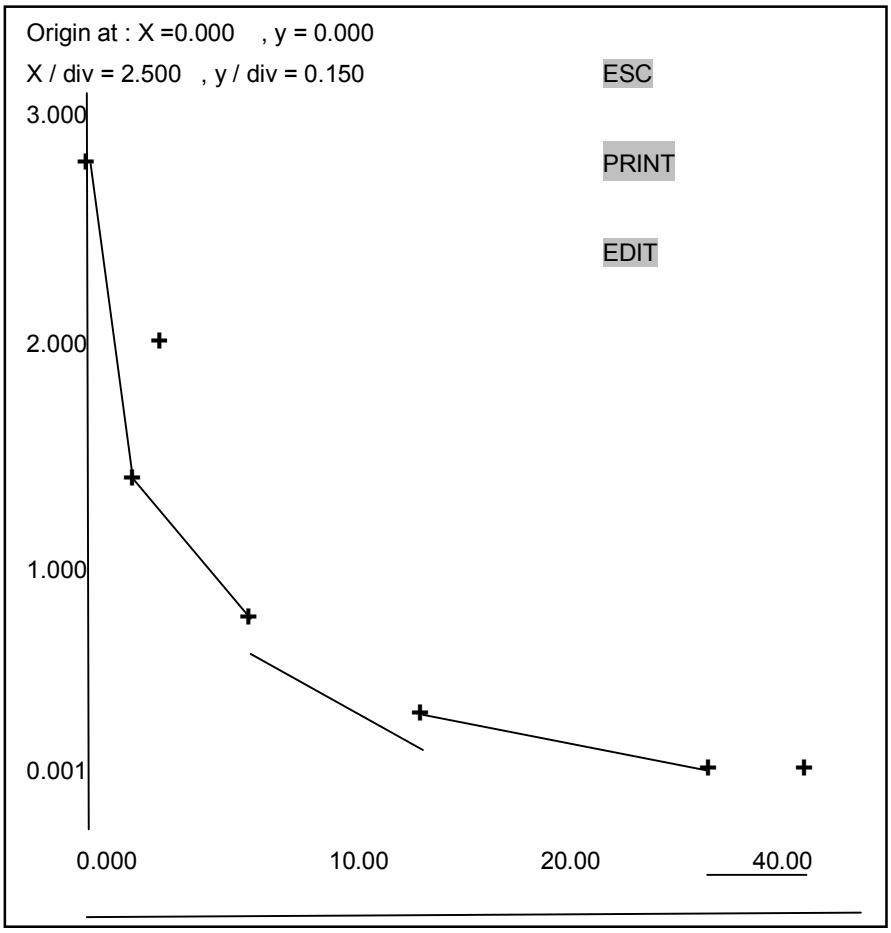
NOTE: User can view the Saved Graph from the Test parameter screen before running the same test.



On selecting GRAPH option, it will display following screen where user can select "PLOT" option in order to view the Valid GRAPH Screen.



The Graph screen will be displayed as shown below-



11.SAMPLE AND SAMPLE DUPLICATE

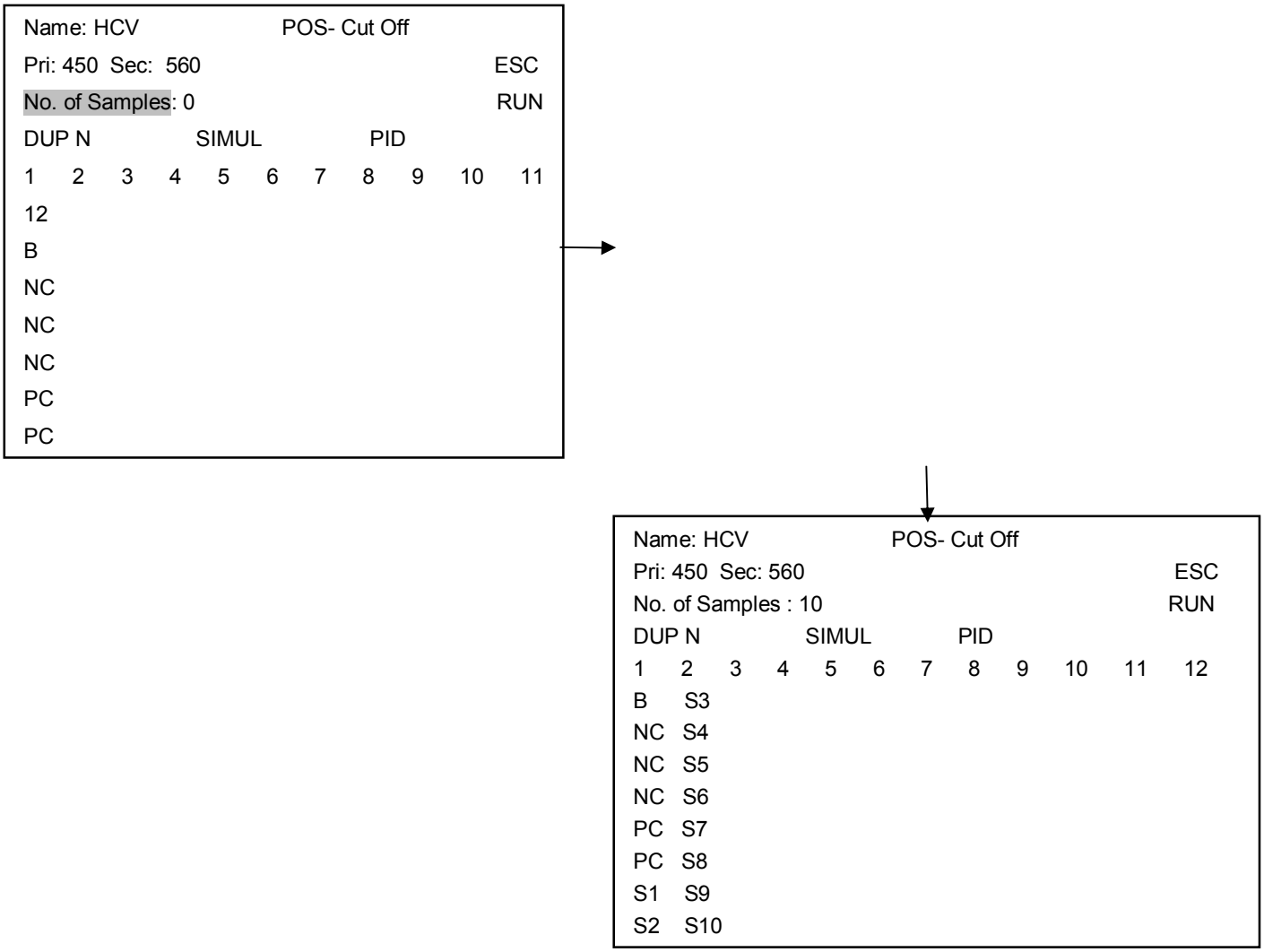
While loading the samples you can load a single sample in single well or a single sample in adjacent two well and finally the instrument will take the average of it as known as Sample Duplicate.

The instrument will load the controls / calibrators automatically in any new test or not accepted test. You have to provide the number of samples. If you are loading single samples keep “DUP”-No. Select “No. of Samples:” to enter total samples.

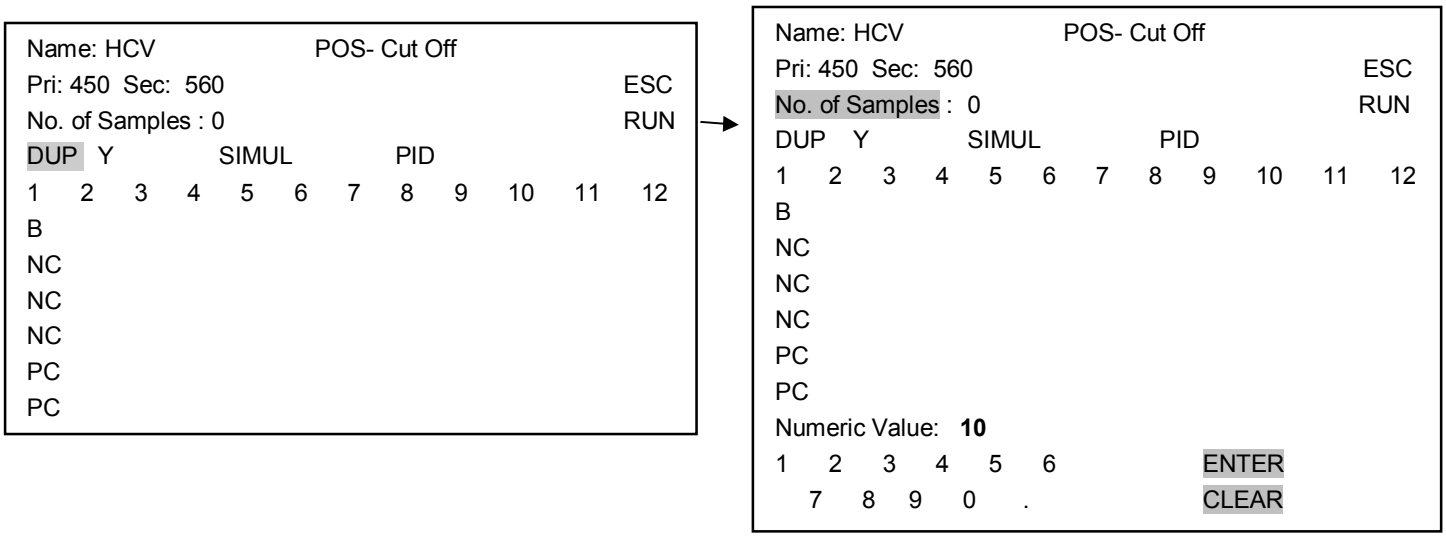
While loading the samples you can load a single sample in single well or a single sample in adjacent two well and finally the instrument will take the average of it known as Sample Duplicate.

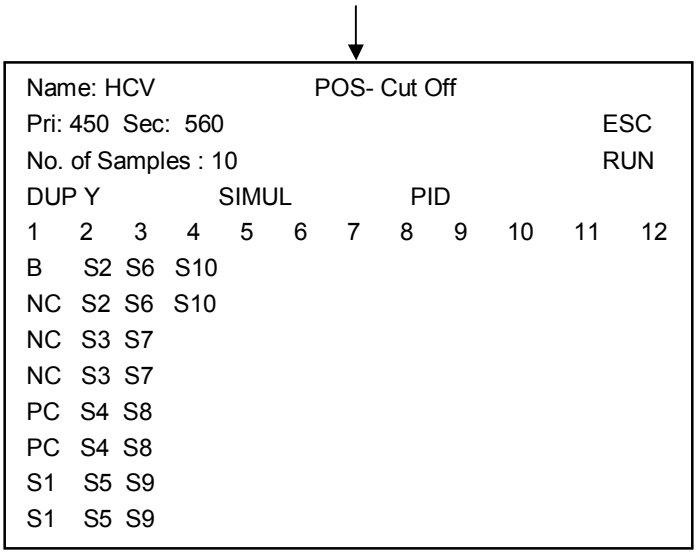
The instrument will load the controls / calibrators automatically in any new test or not accepted test. You have to provide the number of samples. If you are loading single samples keep “DUP”-No. Select “No. of Samples:” to enter total samples.

Name: HCV POS- Cut Off
Pri: 450 Sec: 560 ESC
No. of Samples : 0 RUN
DUP N SIMUL PID
1 2 3 4 5 6 7 8 9 10 11 12
B



If you want to load duplicate samples select "DUP" option and then enter the number of samples by selecting "No. of Samples"





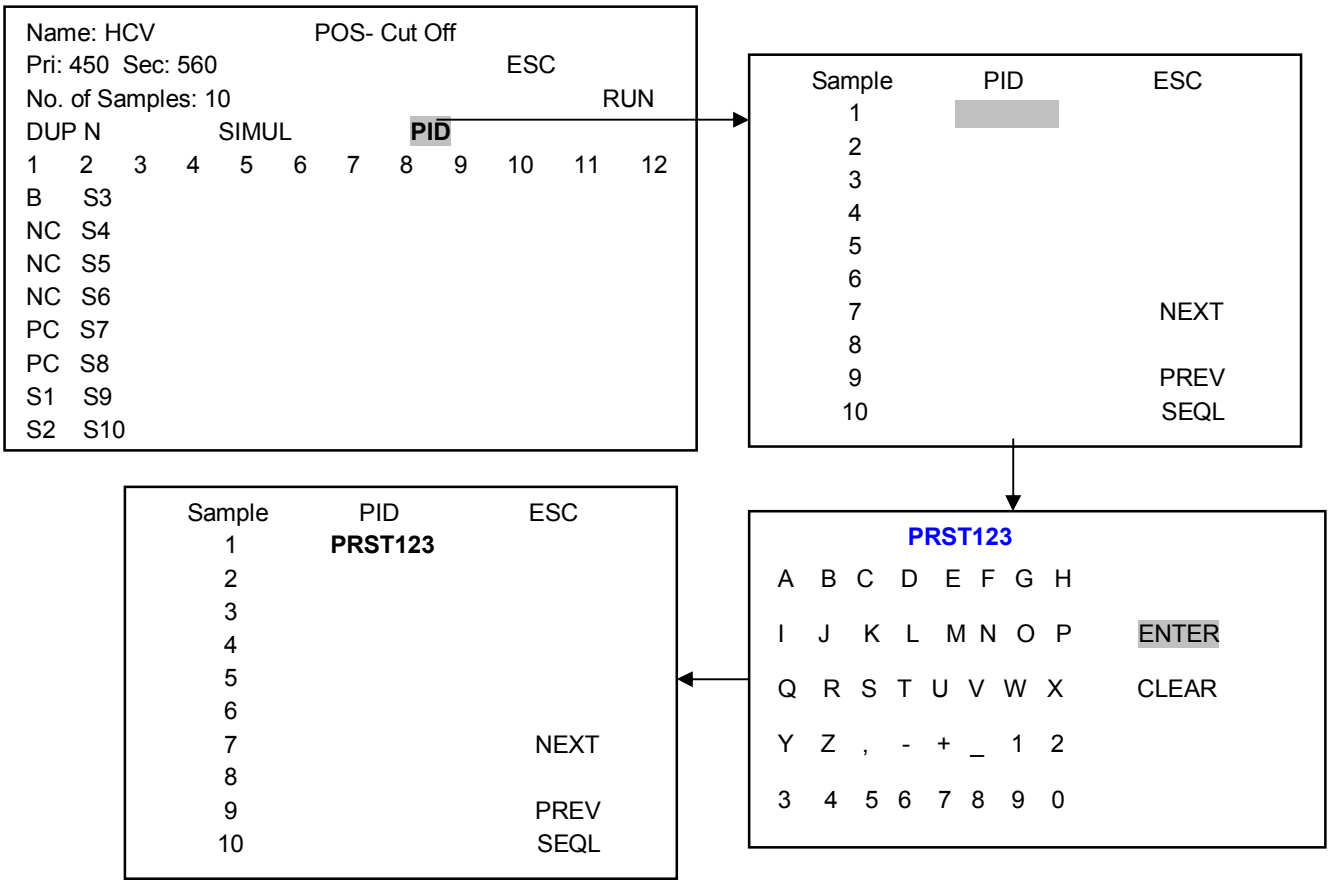
(* Similarly, user can load the samples and Sample Duplicates in all other modes)

12.PATIENT IDENTITY / SAMPLE IDENTITY ENTRY

A.) To enter a patient ID for all samples there is option provided in loading screen shown as "PID".

After entering number of samples either single or duplicate, select "PID".

A) Individual PID entry -



One by one you can enter name of each patient. The character length of PID is only 7 characters in the following combinations –

Since PID of the Patient is entered with the help of Alpha-numeric characters, the combination must be as mentioned below.

Alphabets	Numbers
4	3
3	4
2	5

For example -

1. In the first combination, user can enter PID with 4 Alphabets and 3 Numbers. That means, entered PID should be PQRS123
2. Similarly, for the second combination, user can enter PID with 3 Alphabets and 4 Numbers. And therefore, entered PID will be UTV1234
3. And for the third combination, user can enter PID with 2 Alphabets and 5 Numbers ie. PID will be displayed as RB12345

4. But one can't enter the PID with 1 Alphabet and 6 Numbers since its maximum numeric count is 65500.

(Note: The same combinations should be used during SEQUENTIAL entry also.)

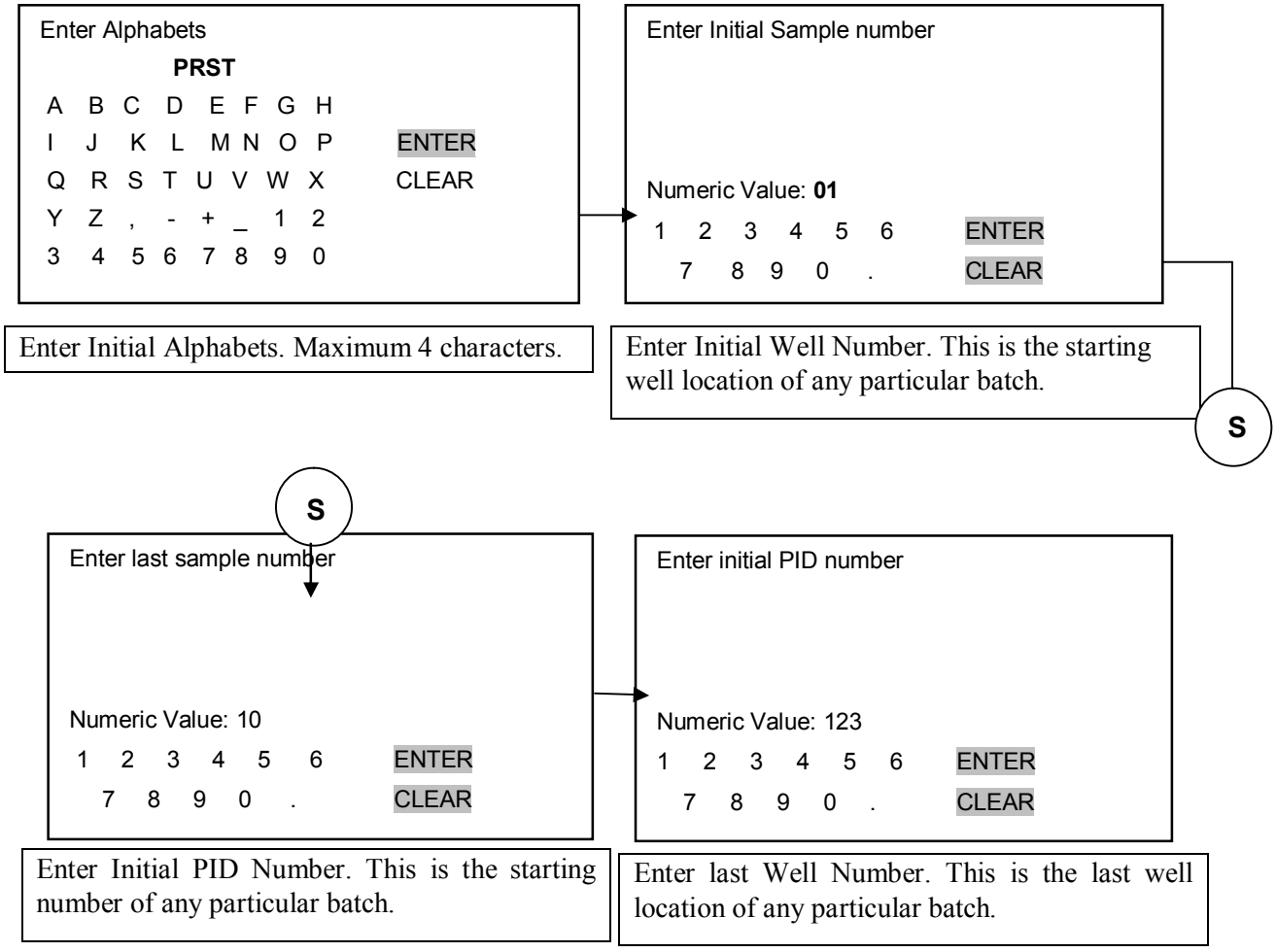
B) Sequential Patient ID Entry

This one by one entry will take more time, therefore one more option to enter Patient Ids is provided. This option is "SEQL" sequential entry.

If you select "PID" option for patient ID entry, the following question appears on the screen:

"Delete Previous PIDs? Yes / No". If you select NO, it will directly load the previously entered PIDs for sample and if you select YES, it will delete the previous PIDs.

Now select 'SEQL', it will display Alphanumeric screen where user can enter different sequential PIDs. Follow the steps below-


Enter Alphabets
PRST
A B C D E F G H
I J K L M N O P
Q R S T U V W X
Y Z , - + _ 1 2
3 4 5 6 7 8 9 0
ENTER
CLEAR
Enter Initial Sample number
Numeric Value: 01
1 2 3 4 5 6
7 8 9 0 .
ENTER
CLEAR
Enter Initial Alphabets. Maximum 4 characters.
Enter Initial Well Number. This is the starting well location of any particular batch.
S
S
Enter last sample number
Numeric Value: 10
1 2 3 4 5 6
7 8 9 0 .
ENTER
CLEAR
Enter initial PID number
Numeric Value: 123
1 2 3 4 5 6
7 8 9 0 .
ENTER
CLEAR
Enter Initial PID Number. This is the starting number of any particular batch.
Enter last Well Number. This is the last well location of any particular batch.

The final screen will appear which displays the sequential IDs of patient samples for the well location that is selected.

Sample	PID	ESC
1	PRST123	
2	PRST124	
3	PRST125	
4	PRST126	
5	PRST127	
6	PRST128	NEXT
7	PRST129	
8	PRST130	PREV
9	PRST131	
10	PRST132	SEQL

Go to the next and previous screen with the help of "NEXT" and "PREV" option present on the screen.

(*NOTE: The entered PID get stored in instrument memory, until you delete it by using option, "Delete previous PIDs? Yes / NO")

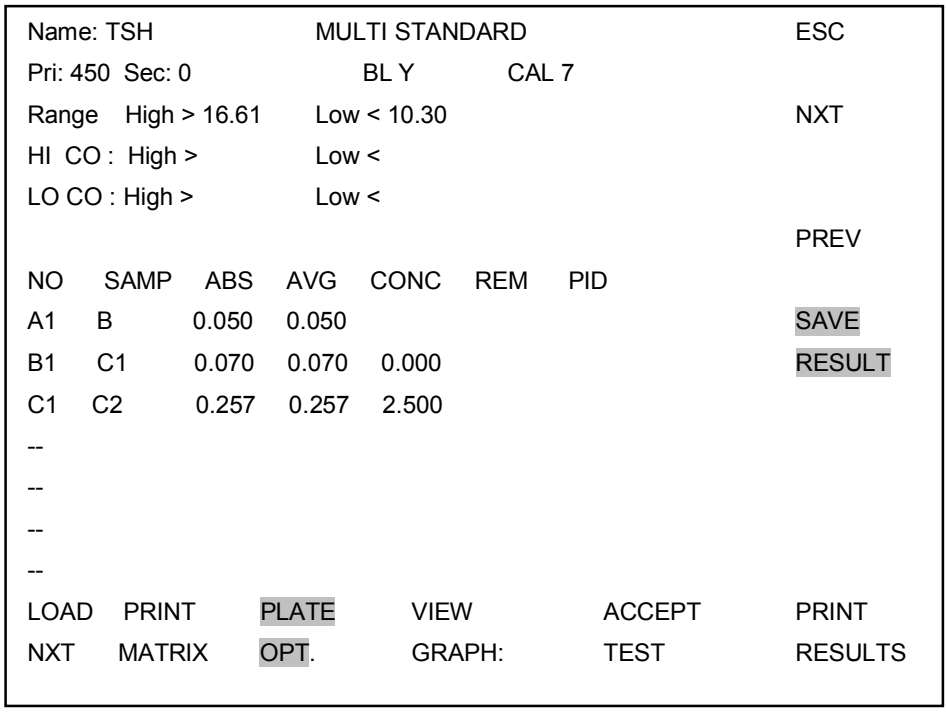
13.SAVE PLATE AND SAVE RESULTS

In all modes of operation, there are two options provided to store results.

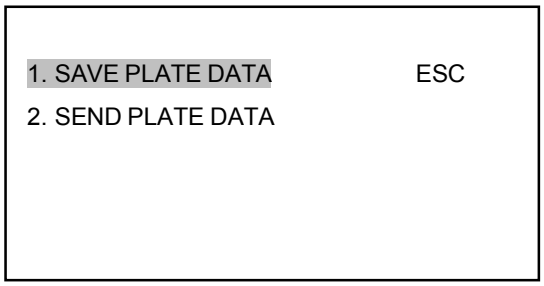
A) In cut Off mode:

Name: HCV			POS- Cut Off				ESC
Pri: 450 Sec: 560			BL Y				
Range PERCENTAGE % 10.00							NXT
NO	SAMP	ABS	AVG	CONC	REM	PID	PREV
A1	B	0.050	0.050				
B1	NC						
--							
--							
--							
--							
--							
--							
PRINT RESULTS			SAVE RESULTS		PRINT MATRIX		PLATE OPT.

B) In Multi standard or any calibrator mode:



If "PLATE OPT."is selected , you will obtain two options.



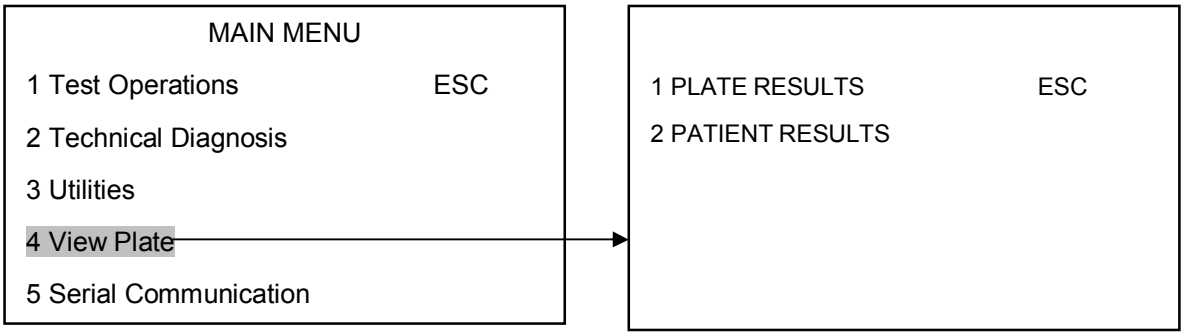
1. "SAVE PLATE DATA", it helps the user to save the entire plate information along with the control/calibrator information (maximum 10 plates data can be saved).

2. "SEND PLATE DATA" is used to send the data from instrument to computer through USB or serial RS232 connection.

If "SAVE RESULT" option is selected the information of samples only except controls/calibrators, with test name, patient ID and date will be saved.

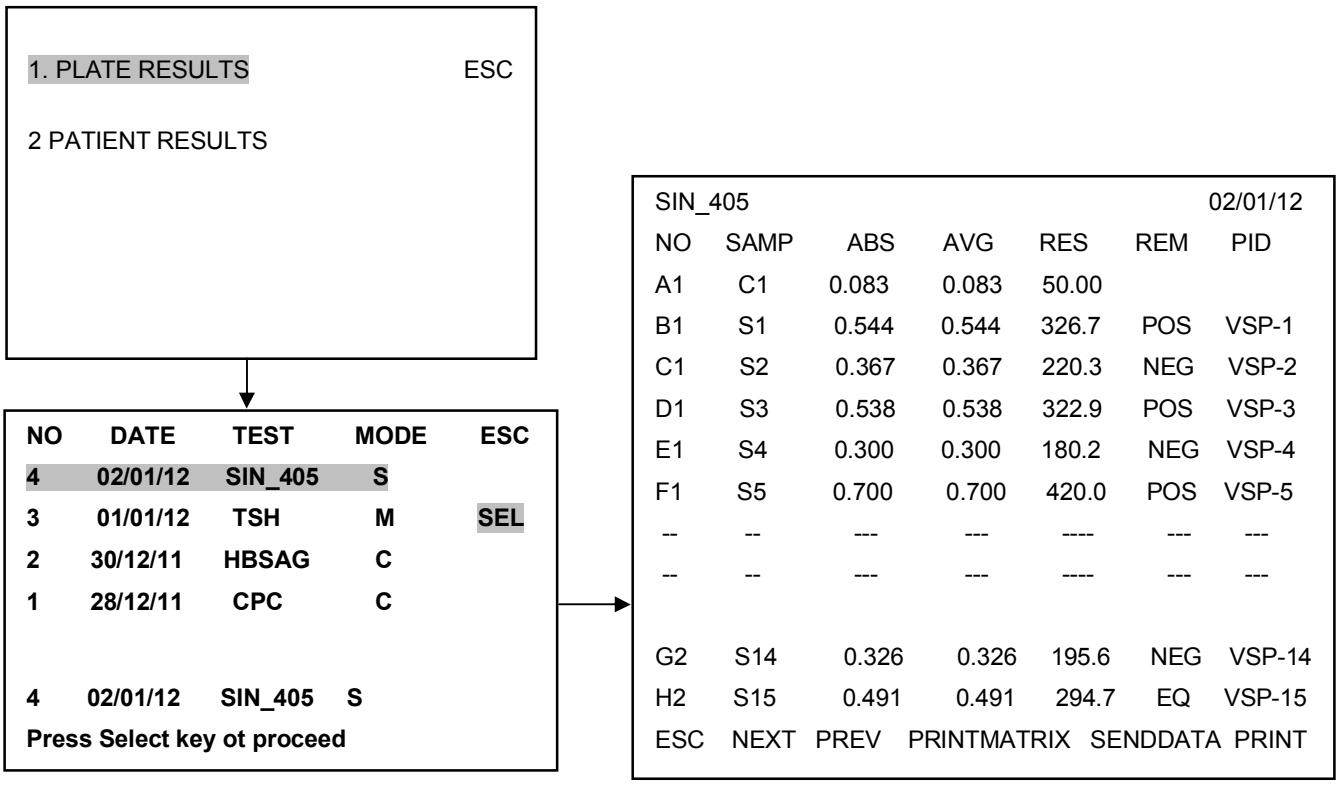
14.VIEW STORED DATA

The stored plate or stored results appear on the screen by selecting option "View Plate" in "MAIN MENU".



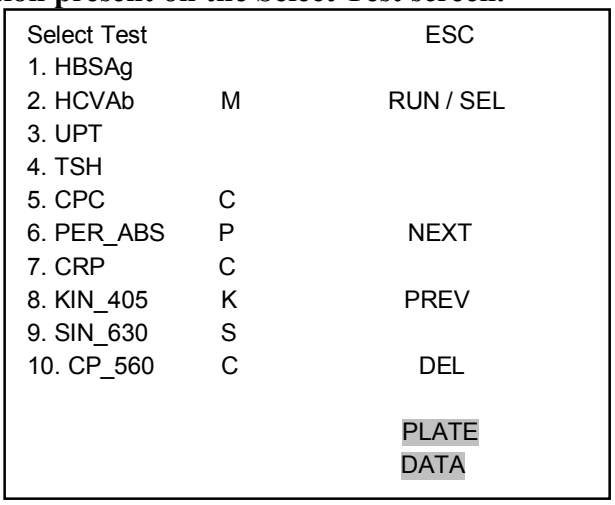
14.1. PLATE RESULT:

It displays the details of stored plate (last 10 plates) with date, test name and mode of operation in descending order. User can select any test to view its plate results by selecting this option.


1. PLATE RESULTS ESC
2 PATIENT RESULTS
NO DATE TEST MODE ESC
4 02/01/12 SIN_405 S
3 01/01/12 TSH M SEL
2 30/12/11 HBSAG C
1 28/12/11 CPC C
4 02/01/12 SIN_405 S
Press Select key ot proceed
SIN_405 02/01/12
NO SAMP ABS AVG RES REM PID
A1 C1 0.083 0.083 50.00
B1 S1 0.544 0.544 326.7 POS VSP-1
C1 S2 0.367 0.367 220.3 NEG VSP-2
D1 S3 0.538 0.538 322.9 POS VSP-3
E1 S4 0.300 0.300 180.2 NEG VSP-4
F1 S5 0.700 0.700 420.0 POS VSP-5
G2 S14 0.326 0.326 195.6 NEG VSP-14
H2 S15 0.491 0.491 294.7 EQ VSP-15
ESC NEXT PREV PRINTMATRIX SENDDATA PRINT

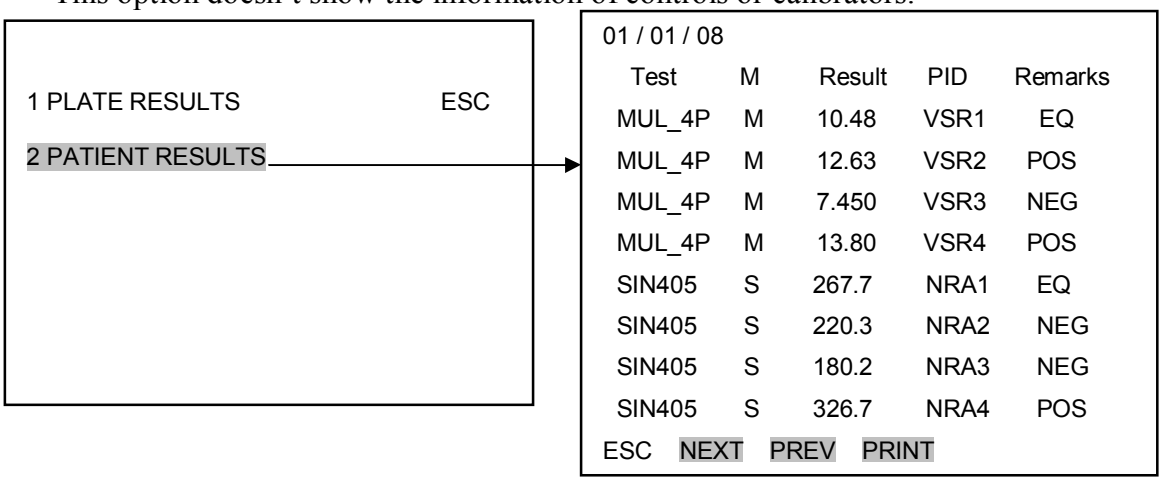
"Print Matrix" will print the details of entire plate in matrix format as explained earlier.
"Print" will print only the data displayed on screen.
"Send data" can be used to send the data from instrument to computer through USB or serial RS232 connection.

Note: User can directly view the details of Plate Results by accessing it through Plate Data option present on the Select Test screen.



14.3. PATIENT RESULTS

It will show the details of all samples, saved in memory using option "SAVE RESULTS" in all different modes, as explain earlier. This option will display the data in table format as shown below. Test name, Mode of test operation, result of sample, PID and Remark will appear on the screen. The instrument has a memory to store 2500 sample results.
This option doesn't show the information of controls or calibrators.


1 PLATE RESULTS
ESC
2 PATIENT RESULTS
01 / 01 / 08
Test M Result PID Remarks
MUL_4P M 10.48 VSR1 EQ
MUL_4P M 12.63 VSR2 POS
MUL_4P M 7.450 VSR3 NEG
MUL_4P M 13.80 VSR4 POS
SIN405 S 267.7 NRA1 EQ
SIN405 S 220.3 NRA2 NEG
SIN405 S 180.2 NRA3 NEG
SIN405 S 326.7 NRA4 POS
ESC NEXT PREV PRINT

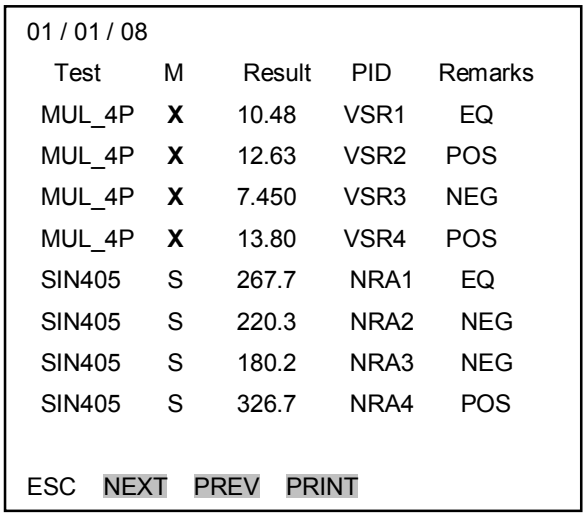
"PRINT" is used to print the details as available on the screen.
"NEXT" and "PREV" options are used to browse through the pages so that one can view all the results one after the other.

NOTE:

1. When there is not enough memory the following message appears:
   "Memory Left for samples- First Samples Deleted"
   The instrument automatically deletes a number of samples that are stored in the beginning

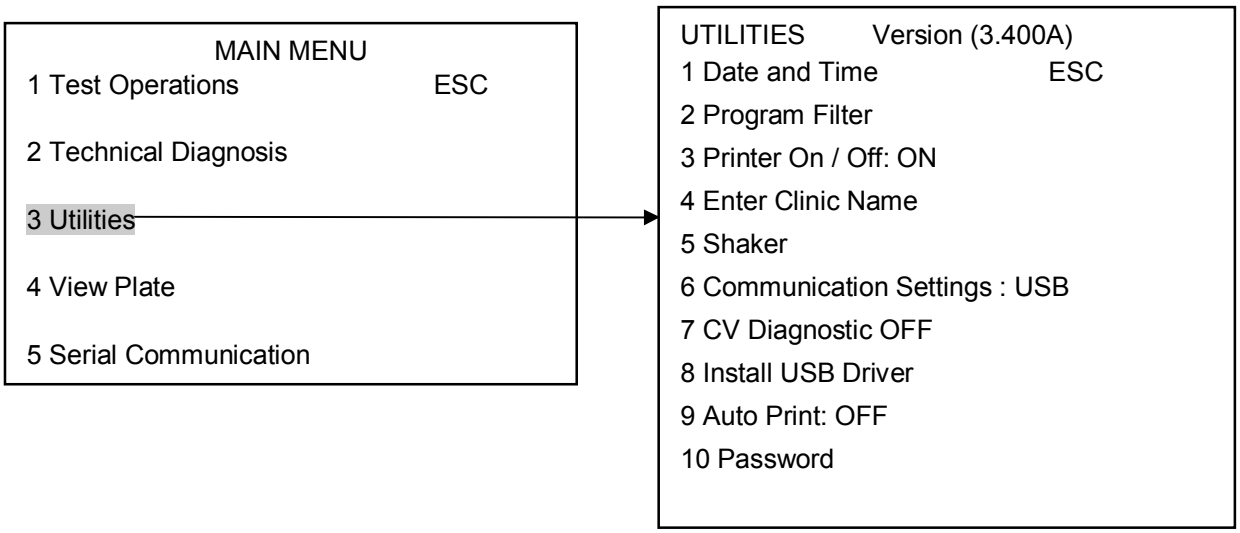
and then save the new samples at that location.

2. If a test is being deleted or edited then previously stored results of that particular test are displayed with their test mode as "X". But test name retained as it is.


01 / 01 / 08
Test M Result PID Remarks
MUL_4P X 10.48 VSR1 EQ
MUL_4P X 12.63 VSR2 POS
MUL_4P X 7.450 VSR3 NEG
MUL_4P X 13.80 VSR4 POS
SIN405 S 267.7 NRA1 EQ
SIN405 S 220.3 NRA2 NEG
SIN405 S 180.2 NRA3 NEG
SIN405 S 326.7 NRA4 POS
ESC NEXT PREV PRINT

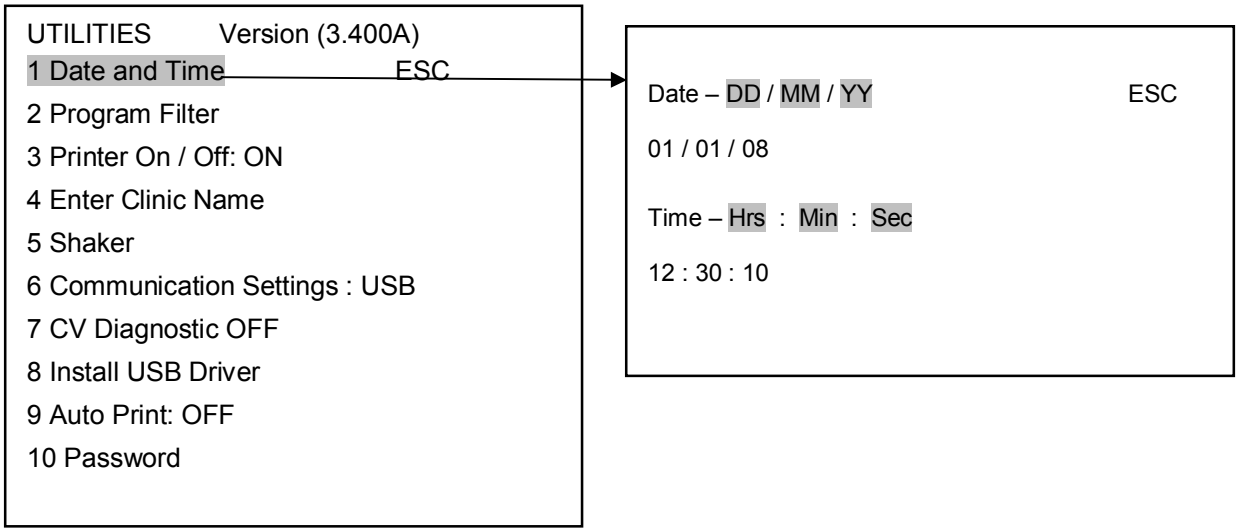
15. UTILITIES

UTILITIES consists of 11 different functions which can be viewed as follows-



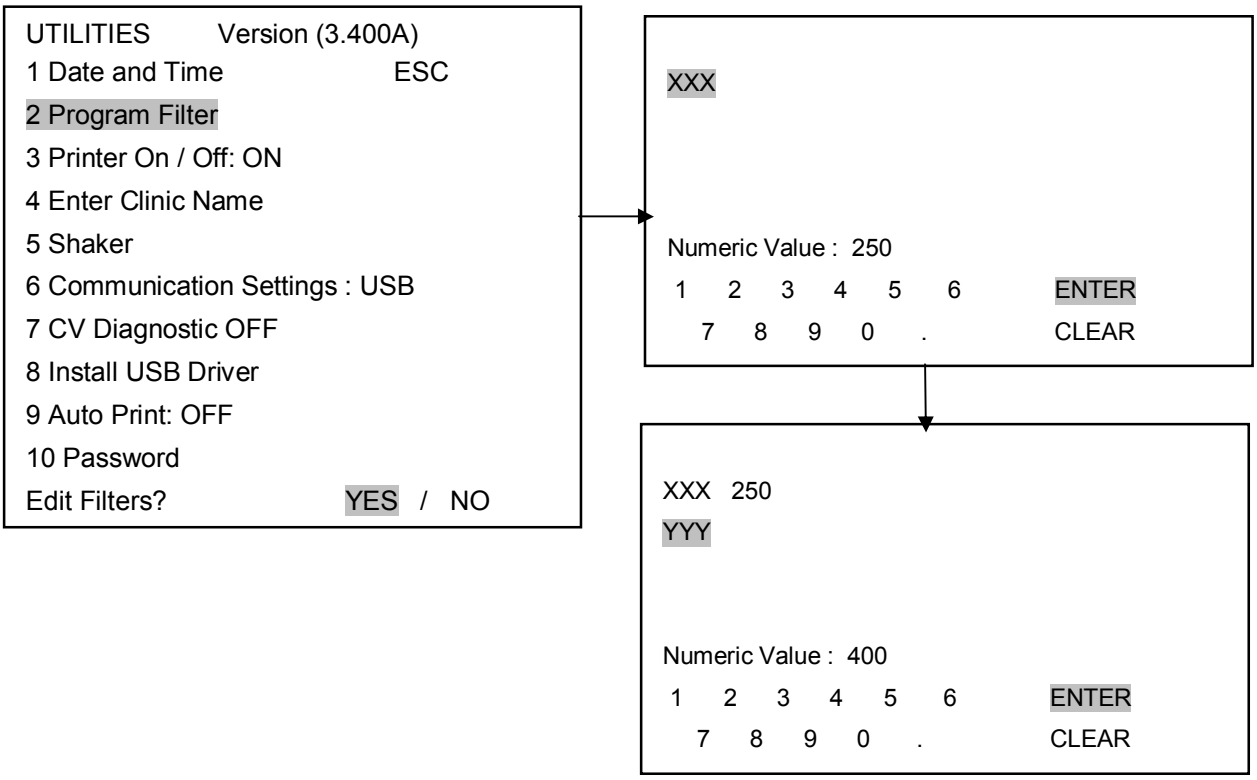
15.1. Date & Time Setting

This Utility helps the user to set current Date and Time.


UTILITIES Version (3.400A)
1 Date and Time ESC
2 Program Filter
3 Printer On / Off: ON
4 Enter Clinic Name
5 Shaker
6 Communication Settings : USB
7 CV Diagnostic OFF
8 Install USB Driver
9 Auto Print: OFF
10 Password
Date – DD / MM / YY ESC
01 / 01 / 08
Time – Hrs : Min : Sec
12 : 30 : 10

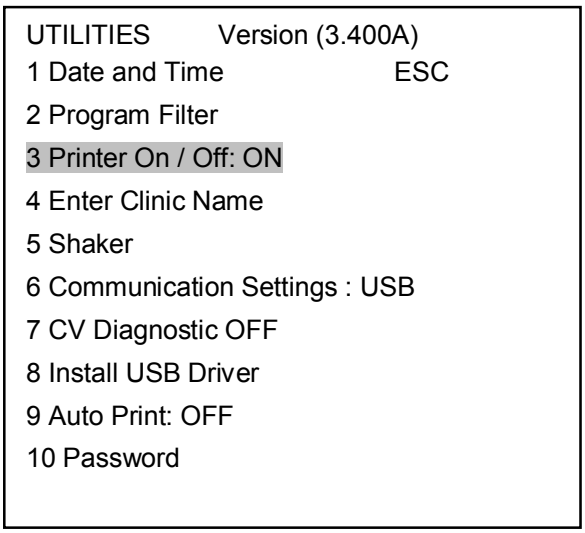
15.2. Program Filter

It consists of two editable filters and thus helps the user to edit the filters if any.


UTILITIES Version (3.400A)
1 Date and Time ESC
2 Program Filter
3 Printer On / Off: ON
4 Enter Clinic Name
5 Shaker
6 Communication Settings : USB
7 CV Diagnostic OFF
8 Install USB Driver
9 Auto Print: OFF
10 Password
Edit Filters? YES / NO
XXX
Numeric Value : 250
1 2 3 4 5 6 ENTER
7 8 9 0 . CLEAR
XXX 250
YYY
Numeric Value : 400
1 2 3 4 5 6 ENTER
7 8 9 0 . CLEAR

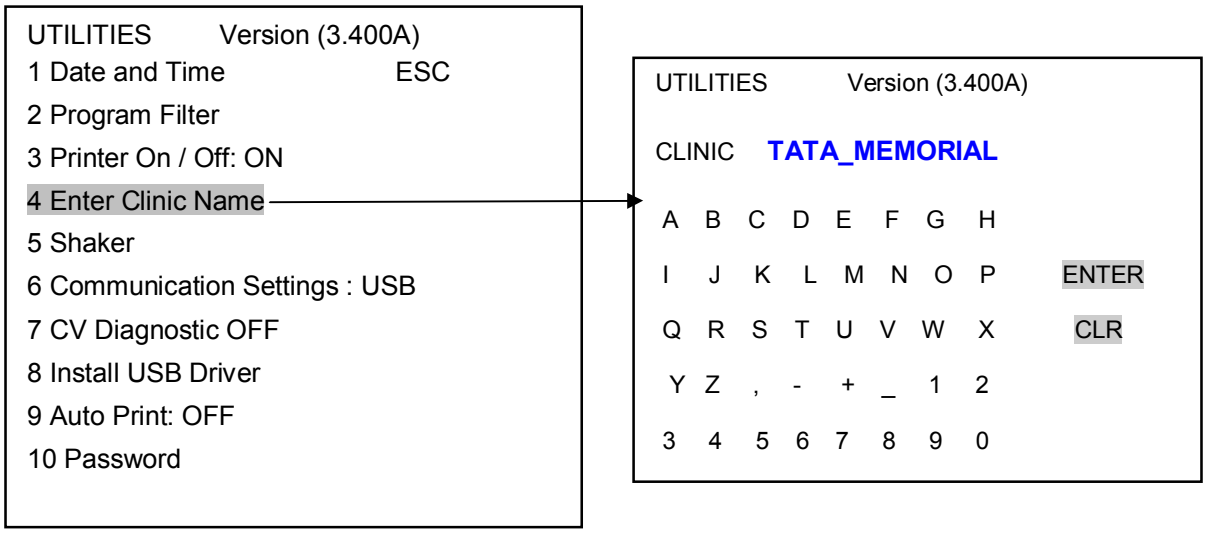
15.3. Printer On / Off setting:

Its a toggle between Printer ON and Printer OFF



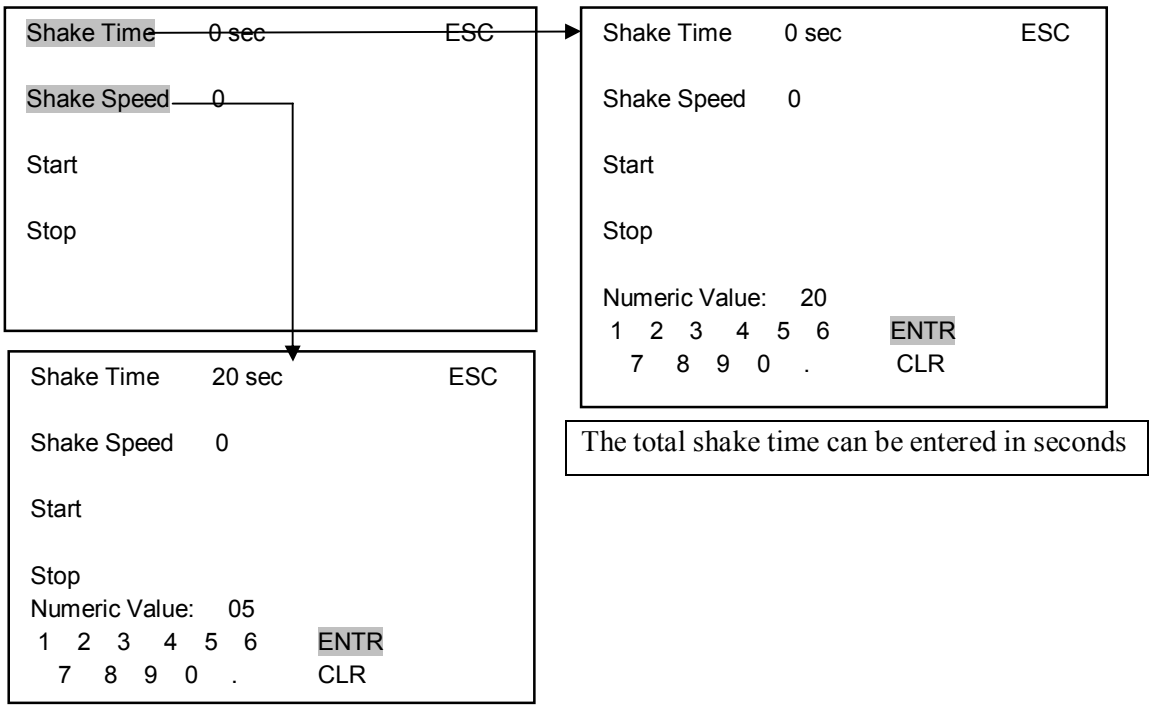
15.4. Enter Clinic Name:

Type your Clinic Name and select “ENTER”. The character length is maximum 19 characters.


UTILITIES Version (3.400A)
1 Date and Time ESC
2 Program Filter
3 Printer On / Off: ON
4 Enter Clinic Name
5 Shaker
6 Communication Settings : USB
7 CV Diagnostic OFF
8 Install USB Driver
9 Auto Print: OFF
10 Password
UTILITIES Version (3.400A)
CLINIC TATA_MEMORIAL
A B C D E F G H
I J K L M N O P ENTER
Q R S T U V W X CLR
Y Z , - + _ 1 2
3 4 5 6 7 8 9 0

15.5. Shaker (Plate Shaking Mode)

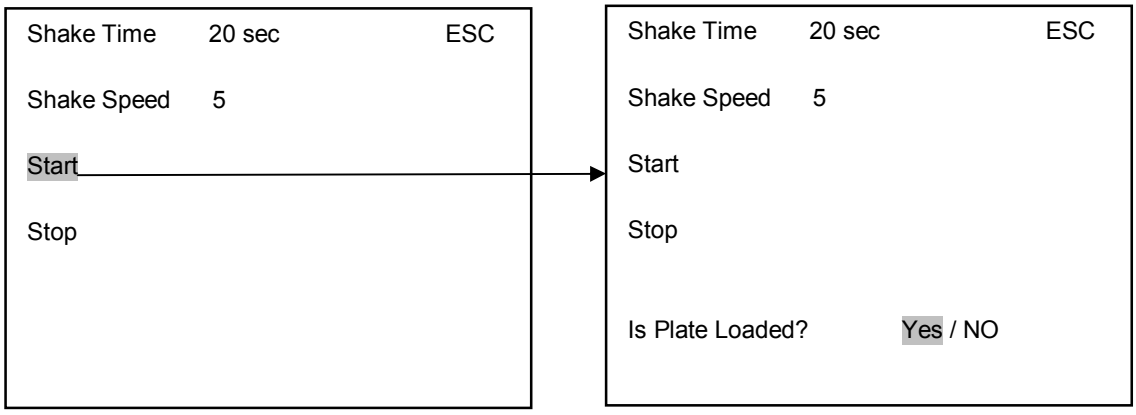
Shaker is used for shaking the plate before running any test. The Shaker screen is displayed as follows -



The total shake time can be entered in seconds

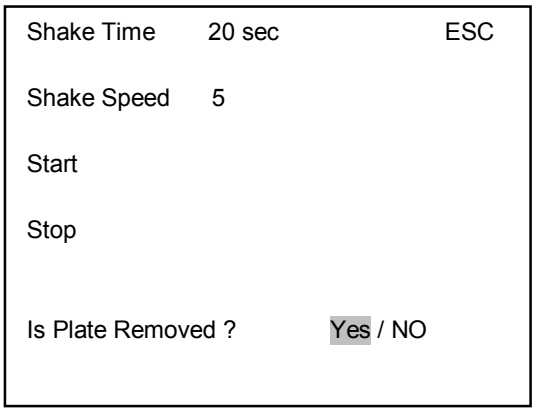
Regarding the "Shake Speed", there are 10 types of speeds. You can choose any speed by entering numbers from 1 to 10. The shaking speed increases as the number increases.

After entering shake time and shake speed, select Start option. When "Start" is selected, the tray will come out and on the screen you will obtain a message "Is plate loaded? Yes / No". Load the plate and select YES option.



After selecting 'YES' the tray will go inside and instrument will do the shaking of plate for the given time period with selected speed.

When the shaking is finished, the plate holder will come out and display a message- "Is plate removed? Yes / No". Remove the plate and select 'YES' to end the process.

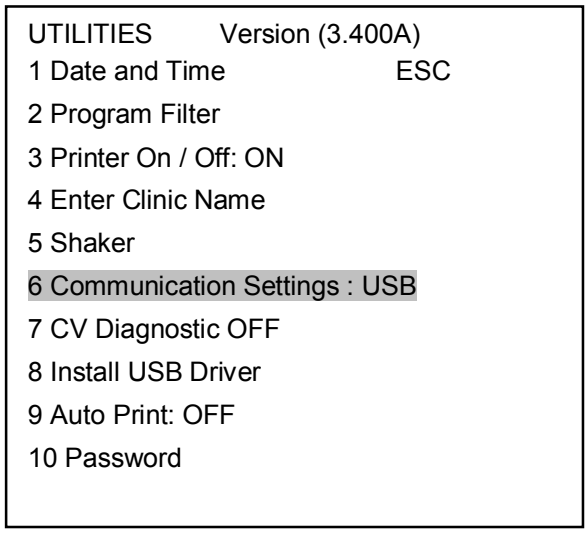


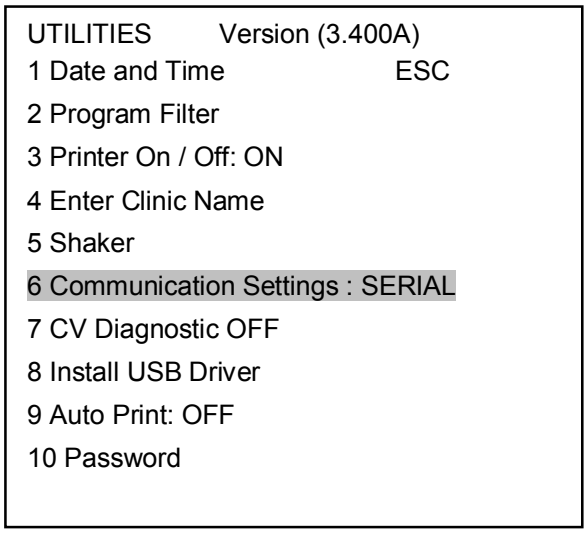
Similarly, to stop the Shaking process in between select "STOP" option present on the screen. After selecting STOP option it will display the message string – 'Is Plate Removed? YES / NO'. Select NO to terminate the ongoing process.

Note: 'HOME' key is also used for directly accessing the shaking mode (ie. SHAKER)

15.6. Communication Settings:

It is a toggle between USB and SERIAL communication. User can either switch to USB or Serial communication by connecting their respective cables.

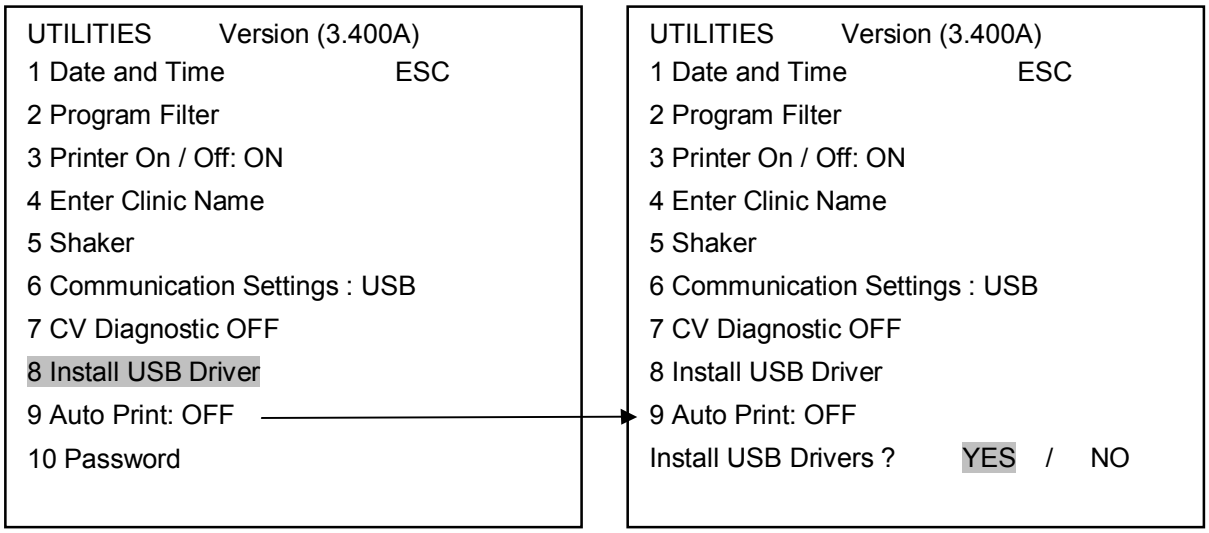




This setting is very important, whenever you want to transfer data from instrument to computer. You can transfer data either using USB or by Serial RS232 cable.

15.8. Install USB Driver:

This option present in the Utilities helps the user to install the USB Drivers in their respective computers. Remember that before installing the USB drivers you must first switch on to the USB communication settings.


UTILITIES Version (3.400A)
1 Date and Time ESC
2 Program Filter
3 Printer On / Off: ON
4 Enter Clinic Name
5 Shaker
6 Communication Settings : USB
7 CV Diagnostic OFF
8 Install USB Driver
9 Auto Print: OFF
10 Password
UTILITIES Version (3.400A)
1 Date and Time ESC
2 Program Filter
3 Printer On / Off: ON
4 Enter Clinic Name
5 Shaker
6 Communication Settings : USB
7 CV Diagnostic OFF
8 Install USB Driver
9 Auto Print: OFF
Install USB Drivers ? YES / NO

15.9. Auto Print: ON

It is a toggle key between Auto Print: ON and Auto Print: OFF.

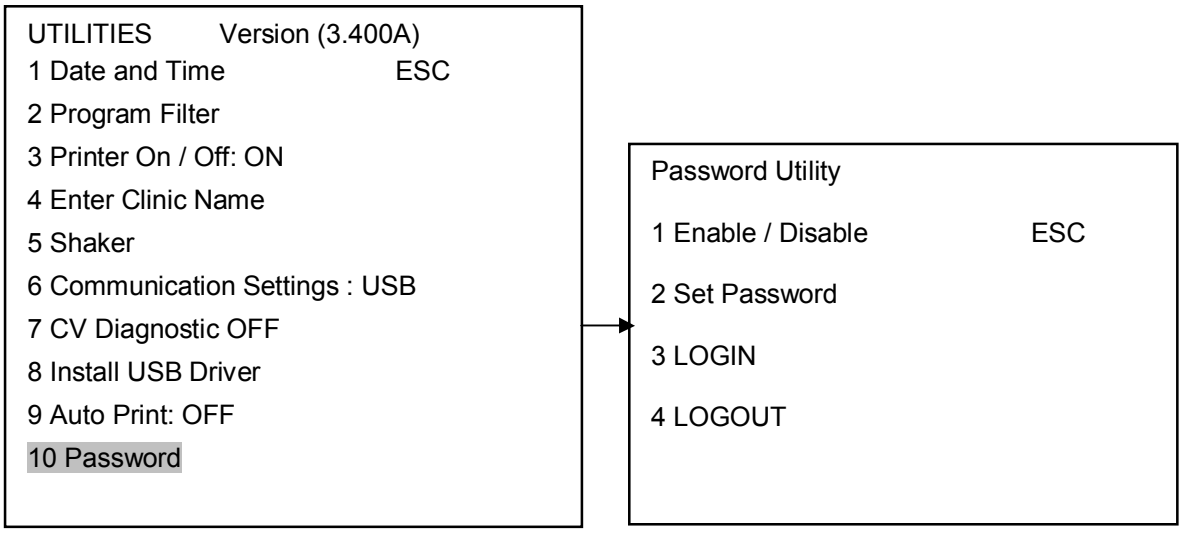
After completing the running process it automatically takes the print of the result and its graph if any in order to maintain the record of the plate run in the form of hard copy.

Auto Print is active in all modes excluding ABS mode. For Auto Print, user must set the printer ON otherwise it will display the error string “Disable printer YES / NO?”

NOTE: The option 8. “CV Diagnostic OFF” is not for users. It is for factory use only.

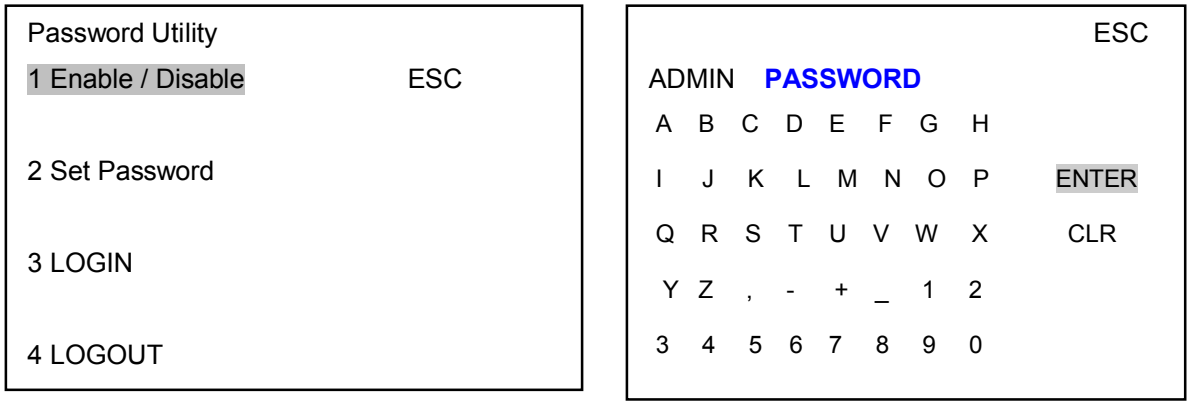
15.10. PASSWORD:

Select Password option in order to Set the Password so that one can't ADD, EDIT, DELETE and SEND / RECEIVE Test records without entering the valid Password.



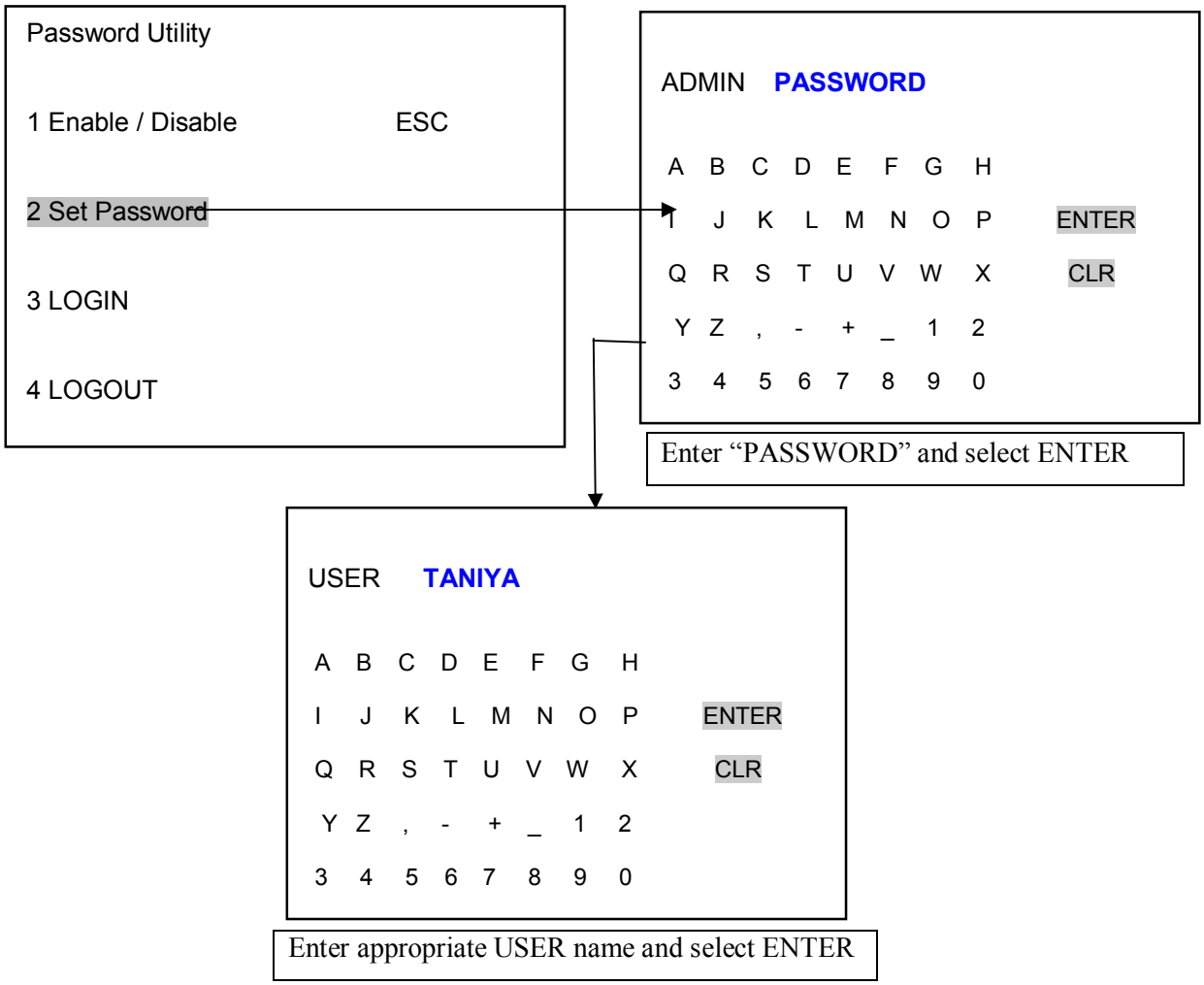
15.10.1. ENABLE / DISABLE:

Enable / Disable helps the user to set the Password or Remove the Password from the Password Utility. Enter Password with the help Alphanumeric screen which is displayed after selecting Enable / Disable option.



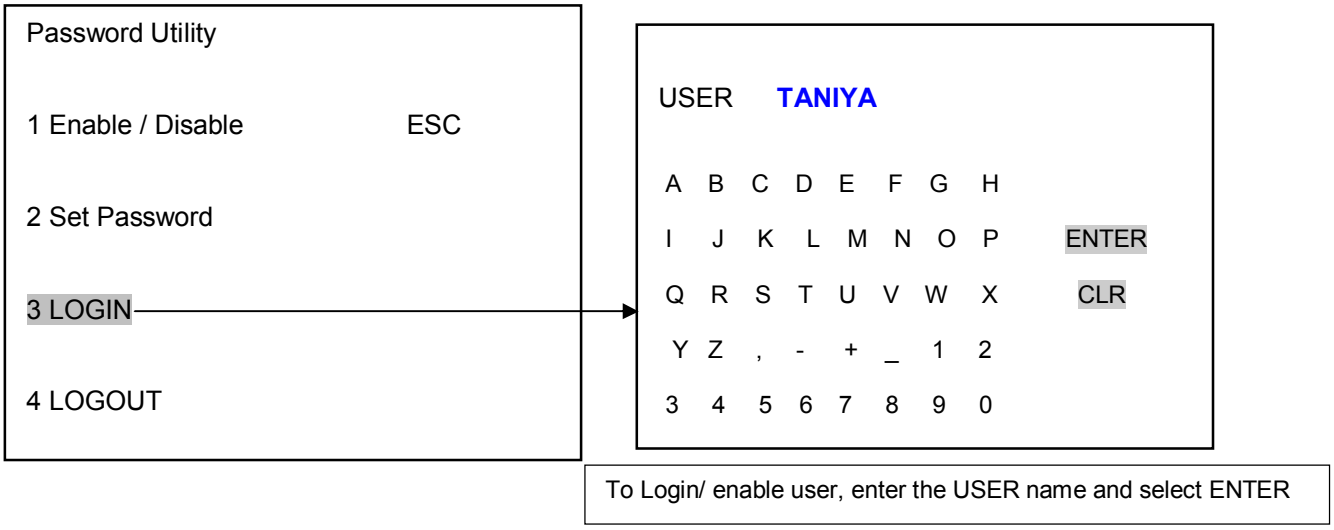
15.10.2. SET PASSWORD:

This option helps to set the PASSWORD along with the USER name.

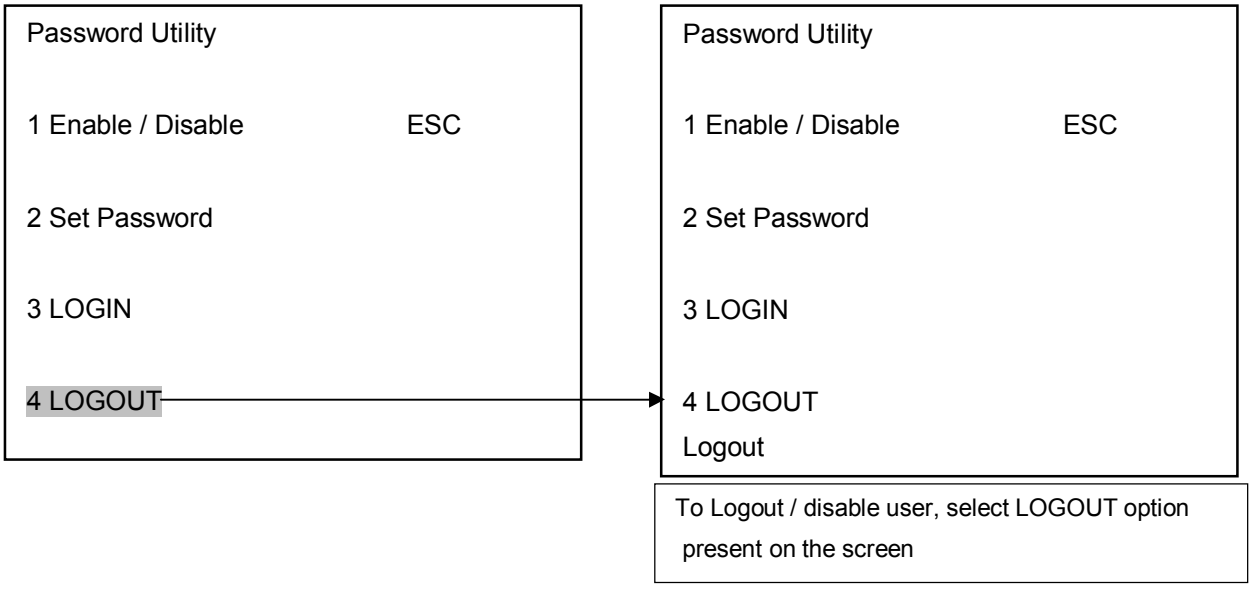

Password Utility
1 Enable / Disable
ESC
2 Set Password
3 LOGIN
4 LOGOUT
ADMIN PASSWORD
A B C D E F G H
I J K L M N O P
ENTER
Q R S T U V W X
CLR
Y Z , - + _ 1 2
3 4 5 6 7 8 9 0
Enter "PASSWORD" and select ENTER
USER TANIYA
A B C D E F G H
I J K L M N O P
ENTER
Q R S T U V W X
CLR
Y Z , - + _ 1 2
3 4 5 6 7 8 9 0
Enter appropriate USER name and select ENTER

15.10.3. LOGIN:

After entering the Password user needs to select LOGIN.

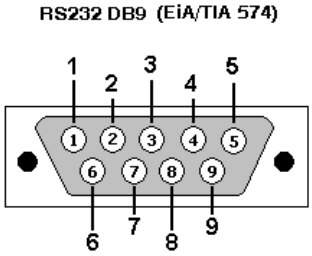

Password Utility
1 Enable / Disable
ESC
2 Set Password
3 LOGIN
4 LOGOUT
USER TANIYA
A B C D E F G H
I J K L M N O P
ENTER
Q R S T U V W X
CLR
Y Z , - + _ 1 2
3 4 5 6 7 8 9 0
To Login/ enable user, enter the USER name and select ENTER

15.10.4. LOGOUT:



16. SERIAL COMMUNICATION

The instrument is equipped with an RS232 serial port for PC configuration ie. User-computer interface. A cable (a NULL-MODEM cable) is required (**not provided**) to link the instrument to PC.

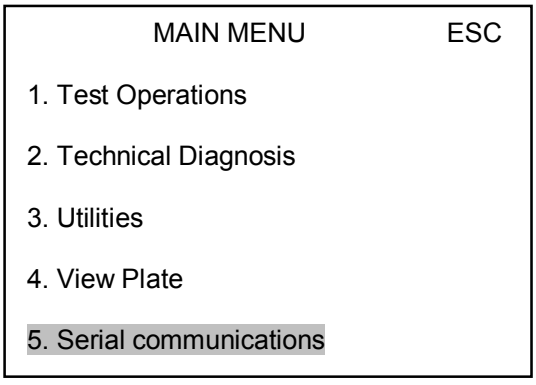


Communication will only start when both ends detect the presence of an active terminal or device.

RS232 port settings in a windows Operating system.

PORT SETTINGS	
Bits per second	: 9600
Data Bits	: 8
Parity None	: None
Stop Bits	: 1
Flow control	: None

There is an option present on the Main menu screen named as SERIAL Communication which is used for transferring data from instrument to the computer and also from instrument to instrument.



16.1. Send Results:

SEND RESULTS helps the user to transfer all the Results stored in the instrument to the computer via Serial Communication.

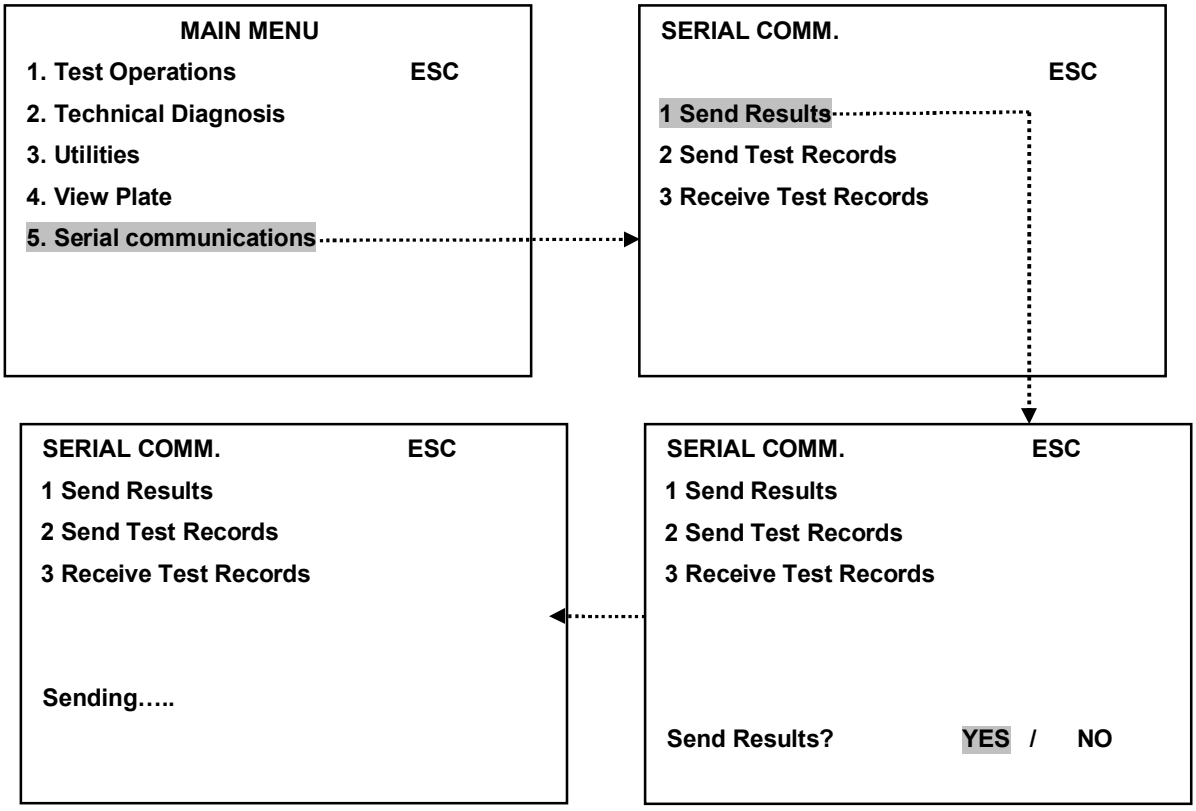
Results can be send either through USB or SERIAL communication.

Before Sending the Results :

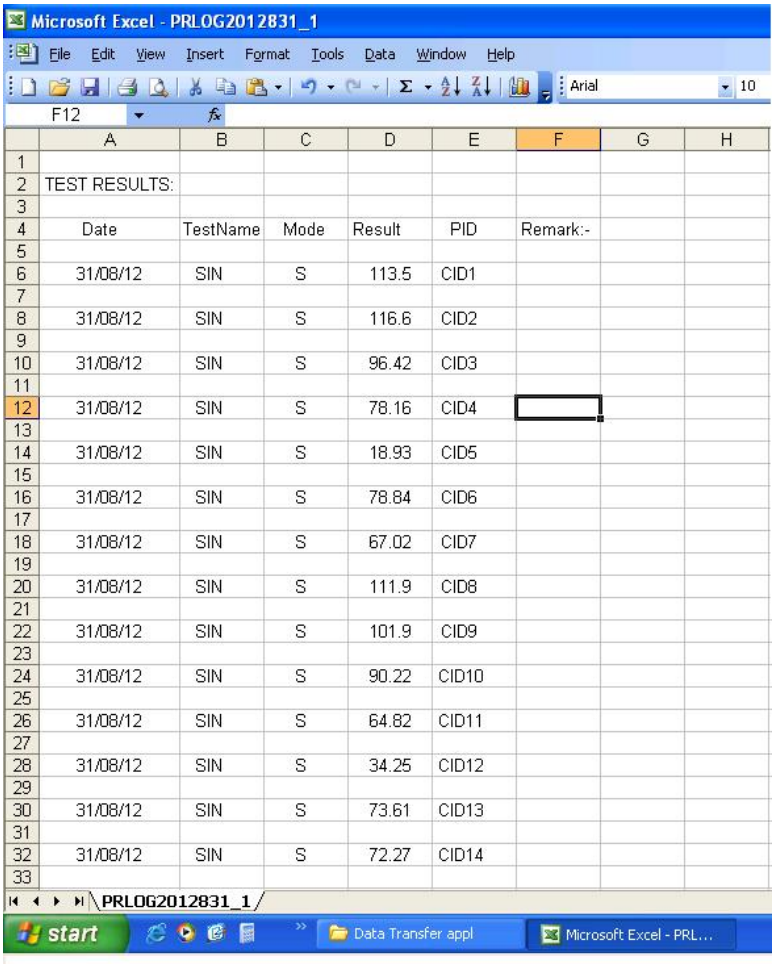
- A driver and the corresponding Data Transfer application must be downloaded on your computer.

Further information can be requested to our distributor or to our technical support Department, IVDInstrumentation.support@diasource.be

-check whether the Serial cable / USB cable is connected to both the ends of the instrument and the computer respectively.



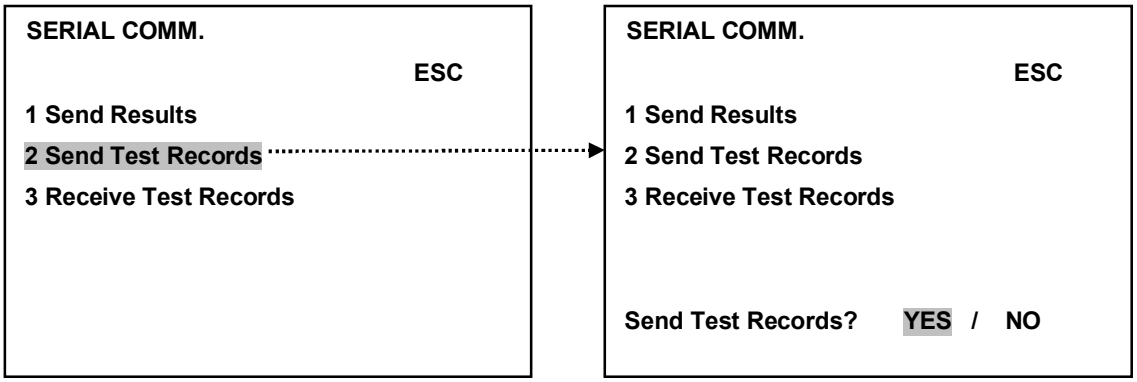
These Results are send through Application, and the Excel file is created as shown below –



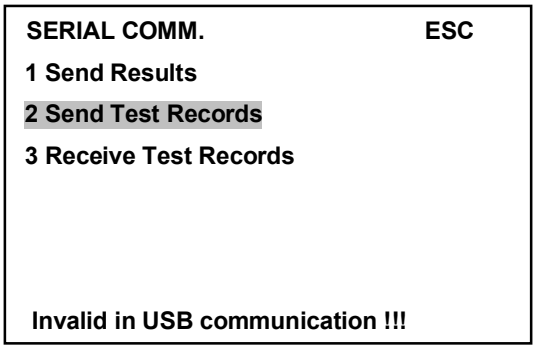
	A	B	C	D	E	F	G	H
1								
2	TEST RESULTS:							
3								
4	Date	TestName	Mode	Result	PID	Remark:-		
5								
6	31/08/12	SIN	S	113.5	CID1			
7								
8	31/08/12	SIN	S	116.6	CID2			
9								
10	31/08/12	SIN	S	96.42	CID3			
11								
12	31/08/12	SIN	S	78.16	CID4			
13								
14	31/08/12	SIN	S	18.93	CID5			
15								
16	31/08/12	SIN	S	78.84	CID6			
17								
18	31/08/12	SIN	S	67.02	CID7			
19								
20	31/08/12	SIN	S	111.9	CID8			
21								
22	31/08/12	SIN	S	101.9	CID9			
23								
24	31/08/12	SIN	S	90.22	CID10			
25								
26	31/08/12	SIN	S	64.82	CID11			
27								
28	31/08/12	SIN	S	34.25	CID12			
29								
30	31/08/12	SIN	S	73.61	CID13			
31								
32	31/08/12	SIN	S	72.27	CID14			
33								

16.2. Send Test Records:

This option helps the user to send the Test Records created in one instrument to another instrument serially with the help of serial cable. And therefore one has to select serial communication in Utilities.

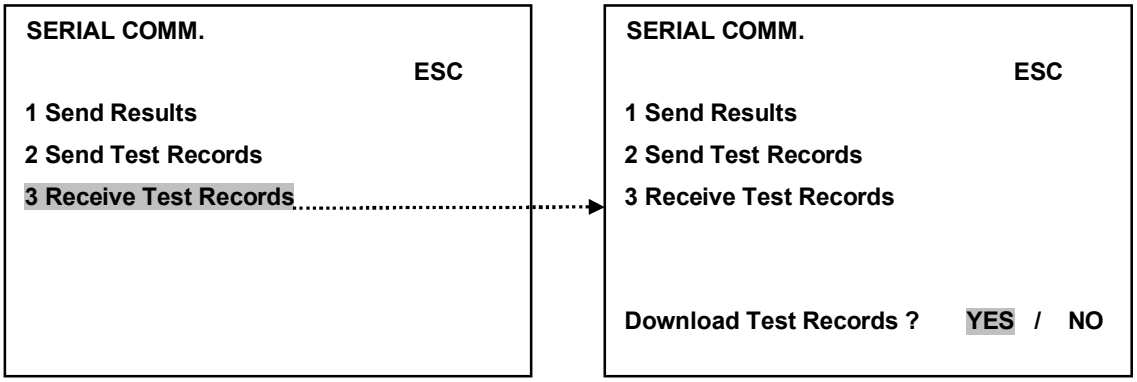


Suppose by default if Serial Communication is set to USB then it will display following screen with msg string.



16.3. Receive Test Records:

This option is used for receiving the Test Records from one instrument to another. On selecting "Receive Test Records"; it will display the string – Download Test Records? Yes / No. Select "Yes" in order to receive the data from the other instrument.

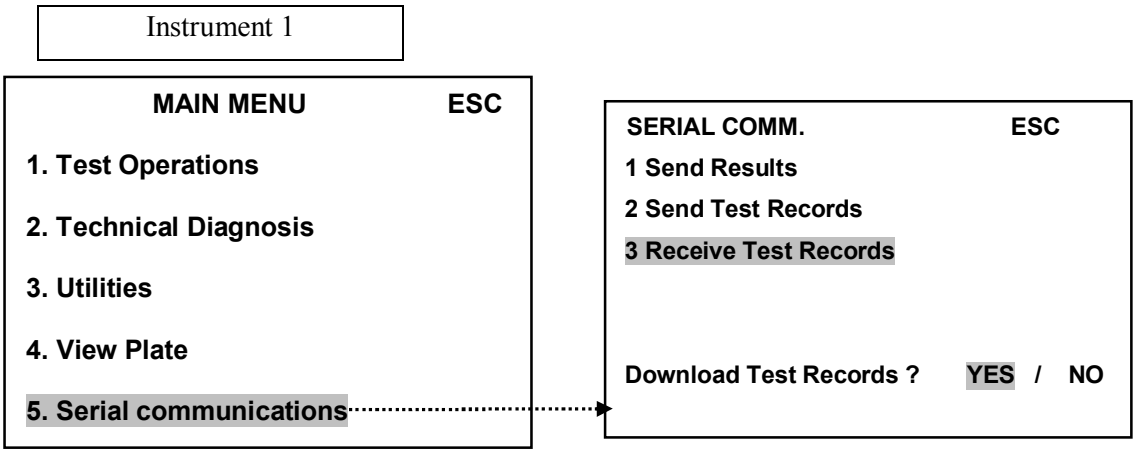


Note: 1. User must first restart the instrument before sending the data from one instrument to another.

2. Remember that while transferring Test Records from one instrument to another one must first select "Receive Test Records" and then select "Send Test Records" in order to send the data from one instrument to another.

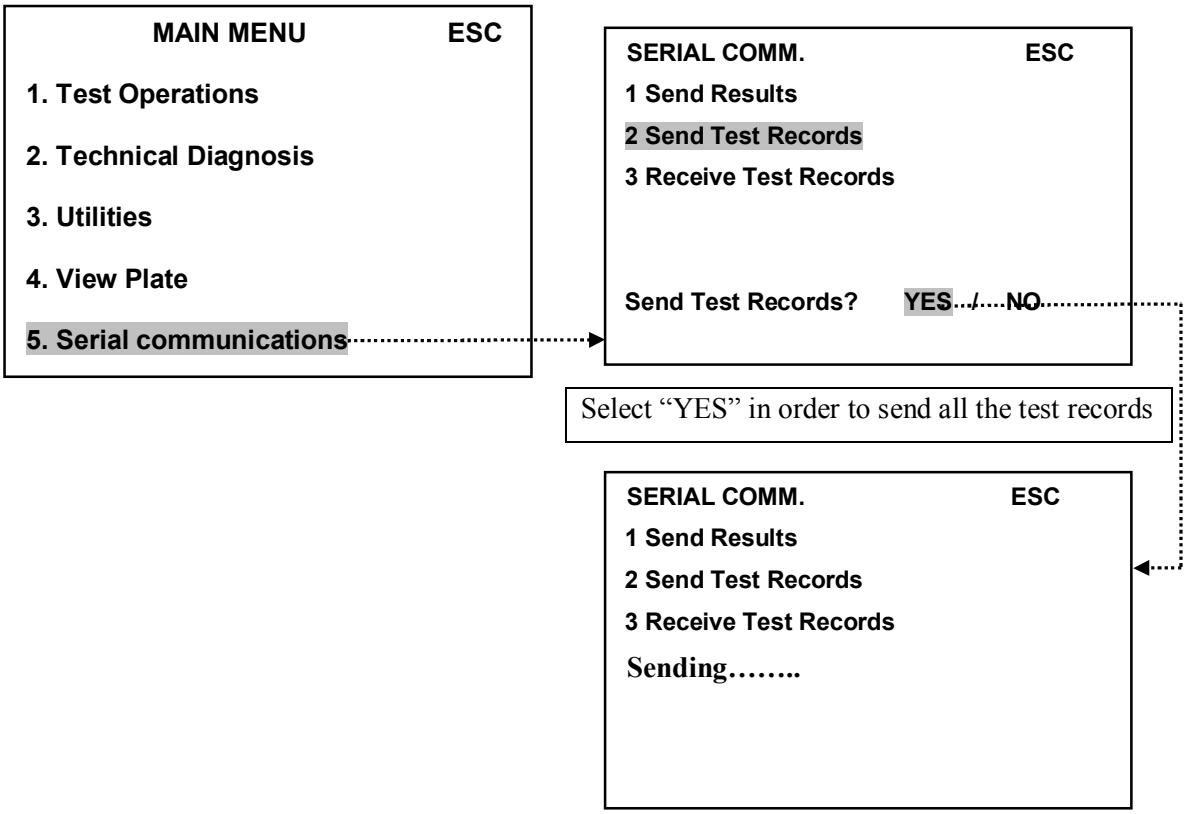
For instance, let us take an example which will show how the Test Records are transferred from instrument to instrument.

Let "Instrument 1" resemble the screen of the Instrument which will receive the Test Records from other instrument. And "Instrument 2" resemble the screen of the Instrument which will send the Test Records to other instrument.



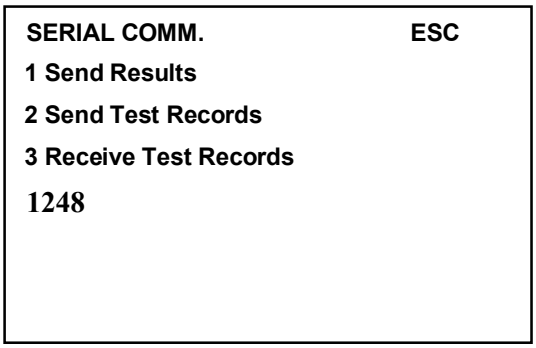
Now for Sending Test Records switch on to Instrument 2.

Instrument 2



And similarly, Instrument 1 will display the following screen which denotes that the instrument is

downloading the Test Records.

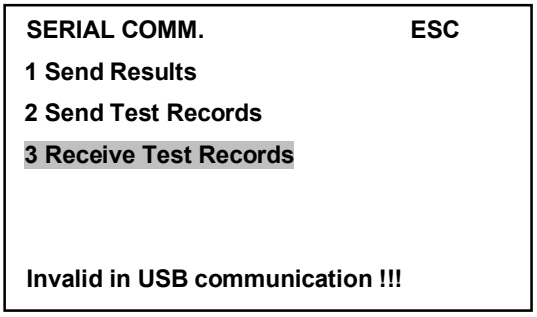


After completing the process of transferring the data, one must restart both the instrument and check for the data transferred between the instruments

In this way, one can transfer Test Records from instrument to instrument.

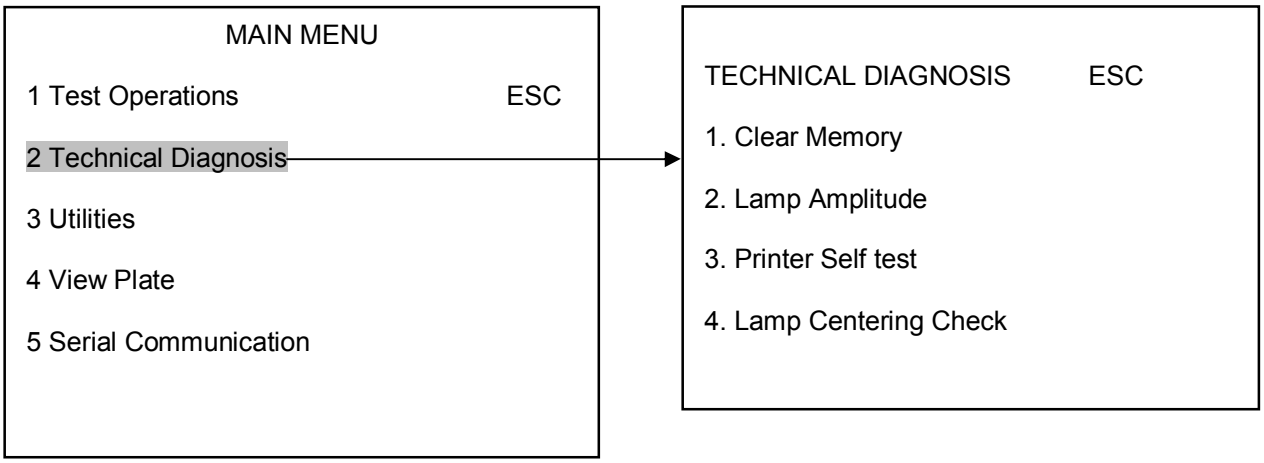
3. User can Send and Receive the Test Records only through serial cable and therefore one has to set the **Serial Communication: SERIAL** in Utilities.

If Serial Communication is set to USB, then it will display following screen –



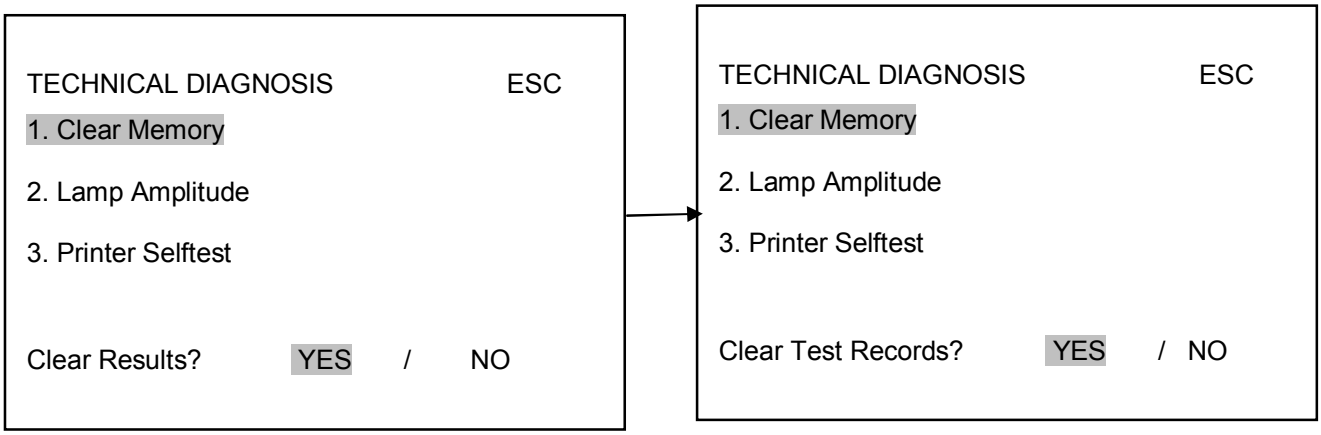
17. TECHNICAL DIAGNOSIS

Technical Diagnosis is present in "Main Menu".



17.1. Clear Memory

This option is used to clear entire saved test records and entire saved patient results along with saved plates. The "Test Records" are the different kind of programmed test that are made in different modes of operation and saved in instrument program memory.



When option “Clear Memory” is selected the instrument will first ask “Clear Results YES / NO”. If “YES”is selected it will only clear saved patient results and saved plates stored in the memory, and shows message “Clearing Memory …”.

This option does not clear the programmed test saved in instrument memory.

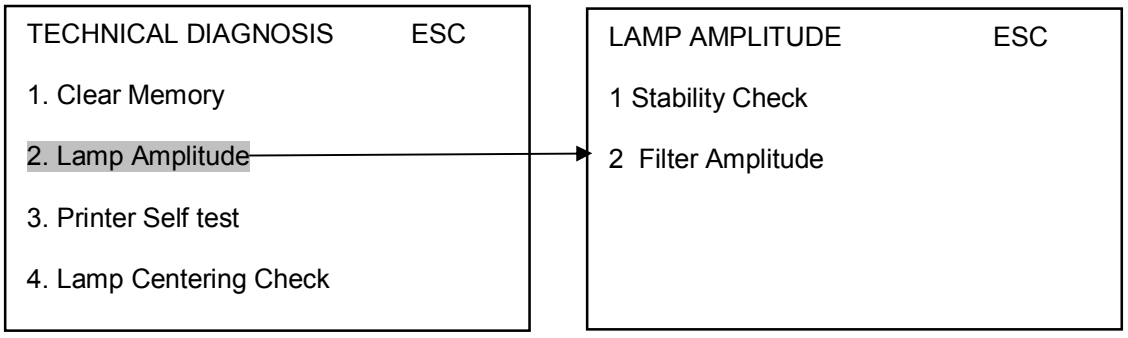
After clearing the memory or if option “NO” is selected the next question appears.

17.2. Lamp Amplitude

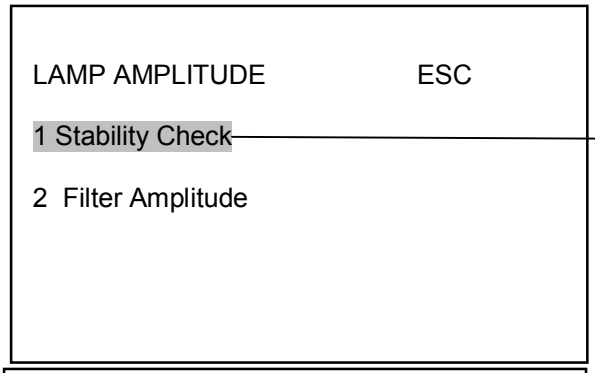
This option is used to check the light gain of filters used in the instrument. There are 8- channels used of same type. This option shows the gain of each channel filter in table format. In the instrument the range of amplitude is from 600.00 to 2450.00. If the amplitude goes below 600.00 for any channel, the message “Amp –Low” will appear on the screen for that particular channel

if the amplitude goes more than 2490.00, than the over range saturation voltage figure of 2500.00 will be passed.

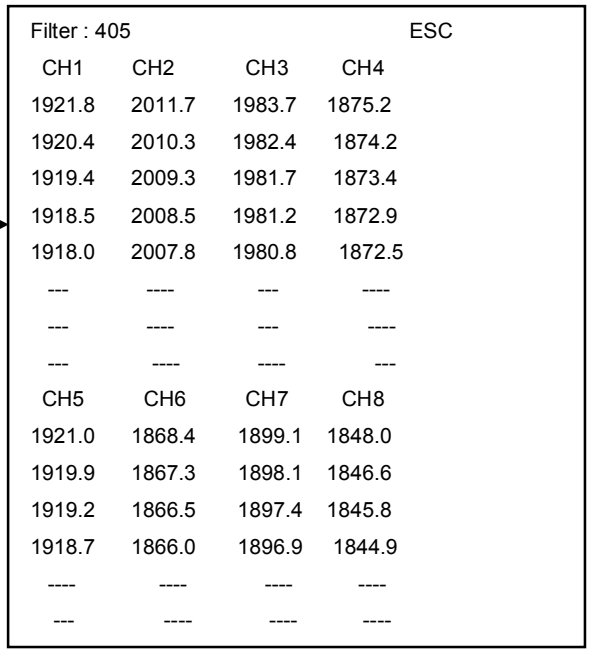
The gains of filters are set within a required range. When you select this option, the lamps will turn ON, tray holder plate will comes out and the instrument will start showing amplitudes (gains) of all filters one by one.

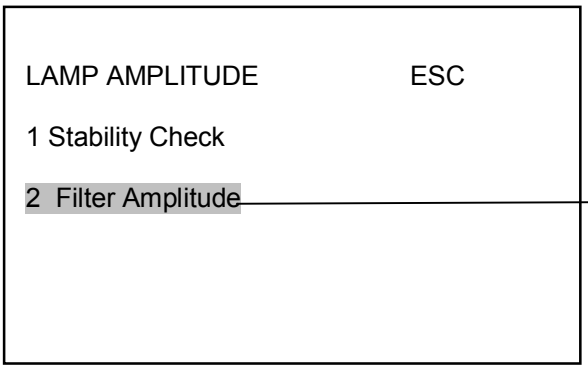


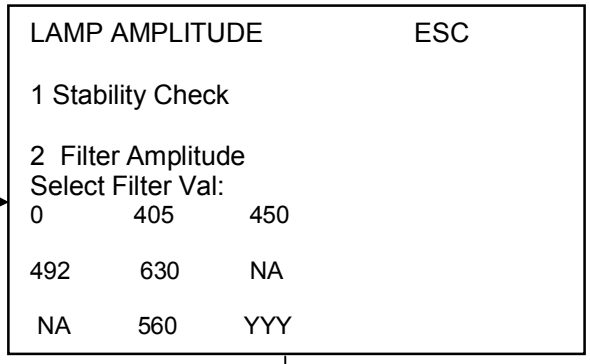
1. Stability Check:



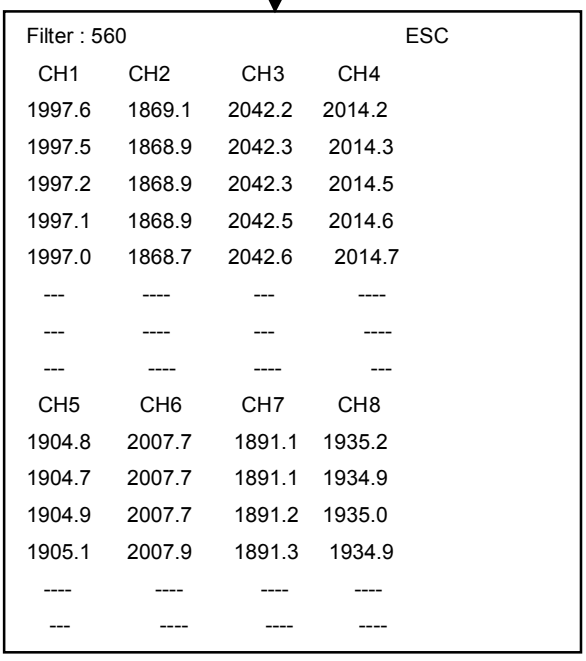
Displays the Lamp Amplitude of all the filters.







Displays the Lamp amplitude of a single selected filter.



17.3. Printer Self test

It is used to check the printing of thermal printer. Is it printing perfectly or not?

When you select this, it will print first two lines of Technical Diagnosis Screen**.**

17.4. Lamp Centering Check:

NOTE: "Lamp Centering Check" is not for users. Do not select this option and don't change any settings otherwise the mechanical alignment will get disturbed, since it is for factory use only.

18. Trouble Shooting

	CAUSE /CORRECTIVE ACTION
1) Printer disabled Disable Printer YES / NO?	You will get this message, if paper is not loaded properly or lever is not at correct position. Check all possibilities. Also check ON LINE and FEED LED glowing or not and when you switch 'ON' the instrument check paper is moving forward or not. If LEDs are not glowing and paper is not moving forward contact service engineer.
2) "Check Light Path!!! CH x" Where 'x' is any channel number X = 1/2/3/4/5/6/7/8	You can get this message in any mode of operation. Before reading absorbance, instrument is checking the filter reference voltages of all 8 channels. If filter voltage of any channel is less than minimum required voltage, it will display a message "Check Light Path!!! CH x". Here 'x' is channel numbers having reference voltage less than minimum required. For ex. If reference voltage of channel 3 is less the message will be displayed "Check Light Path!!! CH 3". It will indicate all channel numbers having less reference voltage, like "Check Light Path!!! CH 1 3 6 " In such a case, there is a possibility of filter gain of that channel is reduced or intensity of lamp of that channel has become poor, so contact factory engineer.
3) Invalid Assay	If in the Cut Off and Multi standard mode the controls and standards are not ok then this error message will appear.
4) Memory Full	If Number of saved tests exceeds the memory limit of 250 tests then delete the unwanted tests and save the test.

5) "Check USB Application on Computer Do you want to continue? YES / NO**"**	Using data receiving application on computer, 1) If you have not connected the data cable (USB or Serial) correctly, you will get this message. 2) If you have selected 'Communication Setting' (ref. 14.5), USB on instrument, and you have selected a 'Serial' communication on computer data receiving application, you will get this message. In such a case select 'USB' communication, on computer and select 'YES' key to transfer data. To avoid this message, connect proper data cable, select the same communication medium (USB or Serial), on computer data receiving application, which you have selected on instrument 'Communication Setting'.
6) Filter Movement Error!!!	Instrument will display this message, if there is problem with MOC sensor PCB or with filter tray stepper motor. The MOC sensors are used to detect the position of filter tray. These two sensors are mounted on bottom of the mechanism. One detects the home position and second detects the each filter position of filter tray. In such a condition we need to check the connection to these sensor and also the connection of stepper motor, which is used to move filter tray.
7) Plate Movement Error!!!	Instrument will display this message, if there is problem with MOC sensor PCB or with plate carrier stepper motor. The MOC sensors are used to detect the position of plate carrier. These two sensors are mounted on top of the mechanism. One detects the home position and second detects the each strip position of plate carrier. In such a condition we need to check the connection to these sensor and also the connection of stepper motor, which is used to move plate carrier.

19. DECONTAMINATION

19.1. Decontamination Procedure

If the instrument is to be shipped after being exposed to potentially hazardous material, it should be decontaminated. The following procedure outlines the method of decontaminating the instrument before packaging and shipment.

19.2. Purpose of Decontamination

Decontamination minimizes the risk to all who come in contact with the instrument during shipping, handling, and servicing.

19.3. General Considerations

Any laboratory instrument that has been used for clinical analysis is considered a biohazard and should be decontaminated prior to handling. Intact skin is generally considered an effective barrier against infectious Organisms; however, small abrasions and cuts may not be always being visible. Prophylactic gloves must be worn when handling instruments that have not been decontaminated. Gloved hands should be considered contaminated at all times and must be kept away from eyes, mouth and nose at all times.

- Mucous membranes are considered prime entry routes for infectious agents. Wear eye protection and a surgical mask when there is a possibility of aerosols.

- Eating and drinking while decontaminating instruments is not advisable.

19.4. Procedure

- A solution of .5% Sodium Hypo Chlorite (NaOCL) solution (Bleach) is used. Commercial bleach is 5% NaOCL; household bleach is 3% NaOCL. When using commercial bleach, use a 10:1 mixture; if using household bleach, a 6:1 mixture is required. This is a caustic solution. It is important to wear gloves and eye protection when handling it.

- Wipe down the carrier and all exposed surfaces of the unit with the bleach solution. Remove the top shroud of the instrument and wipe down the top surface of the instrument base, as well as the inside of the top shroud.

- Rinse all the decontaminated carrier and exposed surfaces will distilled water.

- Reassemble the unit and discard the used gloves and towels.

20. SAFETY CLEARANCE CERTIFICATE

Please complete all information requests on this form prior to returning the instrument to the manufacturer or your local distributor for servicing, repairs or return. Thank you for your co-operation.

Customer _____ **Contact** _____

Address _____ **Position** _____

_____

Dept _____

_____

Tel: _____

_____

Country _____ **Fax:** _____

Post Code

_____

Model No. _____ **Serial No.** _____

_____

Accessories

Returned

_____

Date of Purchase (if known)

_____

Complaint

_____

_____

_____

_____

Has the equipment been exposed to any of the following: (*delete as applicable)

a) Blood, body fluids, pathological specimens *YES/NO

If YES, please specify _____

b) Other Biohazard ***YES/NO**

If YES, Please specify